Canadian Centre for Occupational Health and Safety

Centre canadien d'hygiène et de sécurité au travail

Workplace Hazardous Materials Information System Classification

A Workshop

P88-13E

Canadian Centre
for Occupational Health
and Safety

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Hamilton, Ontario

February 22, 1988

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Canadian Centre
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WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM CLASSIFICATION

A WORKSHOP

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The Canadian Centre
for Occupational Health and Safety

A Workshop

WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM (WHMIS) CLASSIFICATION WORKSHOP

Monday, February 22, 1988
Hamilton Convention Centre, Hamilton, Ontario

AGENDA

8:15 am	Registration and Coffee
9:00 am	Introduction
	CRITERIA REVIEW Geoff Granville, Manager, Toxicology & Material Safety Shell Canada Limited Chairman: Robert Whiting
	CLASSIFICATION OF MATERIAL 1 Robert Whiting, Manager, Material Hazards Canadian Centre for Occupational Health & Safety Chairman: Peter Robson
	APPLICATION OF CRITERIA FOR SKIN & EYE IRRITATION Richard Morris, Toxicologist, Industrial Chemicals & Product Safety Health and Welfare Canada Chairman: Geoff Granville
12:30 pm	Lunch
1:30 pm	ARTICLES Peter Robson, Senior Research Scientist Environmental Science Du Pont Canada Inc Chairman: Marc Baril
	CLASSIFICATION OF MATERIAL 2 Marc Baril, Chef de service du répertoire toxicologique Direction du soutien scientifique et théorique CSST (Commission de la santé et de la sécurité du travail du Québec) Chairman: David Gaylor
	CLASSIFICATION OF IMPORTS FROM USA AND EEC David Gaylor, Manager, Occupational Hygiene C-I-L Inc Chairman: Richard Morris
4:30 pm	Close of Workshop

Welcome

Gordon Atherley
President and Chief Executive Officer
Canadian Centre for Occupational Health and Safety

Welcome to this workshop of the Canadian Centre for Occupational Health and Safety. I am Gordon Atherley, the President of the Centre. The Canadian Centre for Occupational Health and Safety is a tripartite organization; our governing Council of Governors represents governments, employers and labour.

This is your workshop. The product of the workshop is in the form of printed paper. It's the record of what is presented plus the discussions merged in the sort of document that we hope you will feel is yours. The Centre's staff are here to help and to assist in the demonstration of some of our electronics. We are arranging, for tomorrow morning, a visit to the Centre for those of you who would like to come. We would be very pleased to discuss any particular points that you'd like to discuss with us and to show you what we do.

We've been in business since late 1979. The mandate given to us is to act as the information resource in occupational health and safety in both official languages. The mandate has enlarged to the point where we not only provide information, but we are also starting to facilitate workshops. This process of facilitation, bringing people together from labour, management, the professions and government to discuss the issues of occupational health and safety, will be a growing trend for the Centre. The Centre's staff are the information providers, the facilitators but not the decision makers—you are the decision-makers and opinion-givers.

I'm going to hand over to Lillian Vine, manager of the workshop process. She will introduce to you the sessional Chairmen and set the procedure for the day.

Introductions

Lillian Vine
Manager, Committees and Workshops
Canadian Centre for Occupational Health and Safety

Thank you very much Gordon. Welcome to all of you. There will be simultaneous interpretation throughout.

I'd like to tell you how this workshop began. Geoff Granville and Peter Robson had talked with us about the possibility of a workshop on WHMIS classification. As the CMA/CCPA seminars were ending in late November, the request was made. On December 3 at 11 pm, Peter Robson and I spoke by telephone and agreed on the framework. We then prepared the agenda and arranged for presenters. Through our workshop mailing list and

Lillian Vine *continued*

industry contacts we publicized this workshop. Within two weeks, it was sold out and we started planning another.

Working on the planning of this workshop, primarily with Peter, has been a pleasure. The people at this table have been extraordinarily co-operative. I hope that you will find the process today as enjoyable as I found the planning and that the presentations and discussions will assist you with the implementation of WHMIS.

Let me, much too briefly, introduce the panelists.

Geoff Granville graduated with a joint degree in Biochemistry and Toxicology in 1972 from the University of Surrey. Toxicology as a specific degree program was the first course of its type in the world and he was in the first class to graduate. From 1972-74, he worked as a "practical" toxicologist (ie getting bitten by rats and mice) in Shell's Toxicology Lab in the UK. He was transferred to Shell International Petroleum Company's Toxicology Division in 1974, where he performed "deskbound" toxicology until 1981. This consisted of recommending studies, reviewing data and providing risk assessments for Shell's oil and chemical business. In 1981, Shell Canada called, and for the next while he was the Corporate Toxicologist, based in Toronto. In 1984, he was transferred to Calgary as the Manager of Toxicology and Material Safety for Shell Canada Ltd. This job carries the responsibility for the company's Product Safety and MSDS programs, as well as for toxicological matters. Geoff will speak on Criteria Review; the session will be chaired by Robert Whiting.

Bob Whiting is on staff at the Canadian Centre for Occupational Health and Safety. Bob's education includes undergraduate and graduate degrees from the University of Toronto. He holds a BSc in Physics and Chemistry and a MSc and PhD from the Department of Medical Biophysics. Having spent all those years at the University of Toronto, he escaped to British Columbia for post-doctoral work. He was a Fellow of the National Cancer Institute of Canada, in the Cancer Research Centre of the University of British Columbia from 1975-78. He was the recipient of the King George V Silver Jubilee Cancer Research Fellowship for 1975-76. He was a Research Associate in the Environmental Carcinogenesis Unit in BC Cancer Research Centre, a Project Scientist at the Canadian Centre for Occupational Health and Safety, where he is now Manager of the Material Hazards Section, Technical Services.

Lillian Vine *continued*

Richard Morris was born and raised in Vancouver, British Columbia. He did his undergraduate work in British Columbia and Alberta and graduated from the University of Alberta with a BSc in 1963. He did graduate work in physiology at the University of Alaska and at the University of Canterbury in Christchurch, New Zealand, graduating with a PhD in 1974. He worked at Huntingdon Research Centre in England in toxicology and industrial hygiene during the mid-1970s. He taught toxicology and pharmacology at Howard University Medical School in Washington, DC for several years before returning to Canada in 1981 to work for the Department of National Health and Welfare in the Environmental and Occupational Toxicology Division. He has been a toxicologist and health advisor at the Department of National Health and Welfare for the past seven years. During the last five years, part of his duties have involved the WHMIS project, initially as Chairman for the Criteria Working Group and subsequently as the federal advisor on WHMIS classification and related matters.

Peter Robson is the Senior Research Scientist at Du Pont Canada Research Centre in Kingston, with responsibility as Corporate Occupational Hygiene Resource for Du Pont's Canadian Operations. He joined Du Pont Canada in 1964 as Research Chemist at the Kingston Research Centre after graduating in Chemistry in Britain and working for ICI for several years. He had worked in projects involving analytical chemistry, instrument development, and product and process development before specializing in product safety and occupational hygiene over the past 14 years. During that period, he spent two years carrying out occupational health audits of Du Pont plants in the US and Europe while based in the US. He is a Certified Industrial Hygienist under the American Board of Industrial Hygiene and a Director of the Canadian Registration Board of Occupational Hygienists. He has been involved in the development of the Canadian Workplace Hazardous Materials Information Systems since its beginning in 1982.

Marc Baril holds a BSc in Biochemistry, a Masters Degree in Analytical Chemistry and a PhD in Toxicology. Presently, he is the Director of the Toxicological Index. He has worked at CSST (Commission de la santé et de la sécurité du travail du Québec) for the past 8 years. He previously worked at the Ministry of Environment in Quebéc and was also a private consultant.

Lillian Vine *continued*

David Gaylor is Manager, Occupational Hygiene for C-I-L Inc. He manages C-I-L's Regional Occupational Hygiene Program (seven regional hygienists serve 6,000 employees in 100 plus locations across the country). He has a Degree in Chemical Engineering from the University of Waterloo and a Master of Engineering, Industrial Hygiene and Safety Engineering from the University of Toronto. He provided primarily environmental engineering services to C-I-L mercury cell chloralkali plants from 1976-80. He has been part of C-I-L's Occupational Health group since 1981.

When the WHMIS process started several years ago, the people at this table were involved. WHMIS is due to be implemented in October of this year. People are anxious to be ready—to know how to do what needs to be done. When Geoff and Peter first came to us, they said there are needs; there is much to be gained from bringing people together and to look at the skills they're going to need, to look at what needs to be done, and to see how classification is done. From the response we've had, it is obvious they were absolutely right—there is a need and there is a lot of interest. We're very fortunate to have with us the people who are going to help you get that step further and make the process work smoothly for Canada.

The first session entitled Criteria Review will be chaired by Bob Whiting; Geoff Granville is the speaker.

May I introduce Martin O'Connell. Martin O'Connell is the Chairman of the Council of Governors, the tripartite governing Council of the Centre; he was the Minister of Labour when the Centre was coming into existence. He, as is Council, is very supportive of the workshop process which brings people together to find common ground. Martin, thank you for coming.

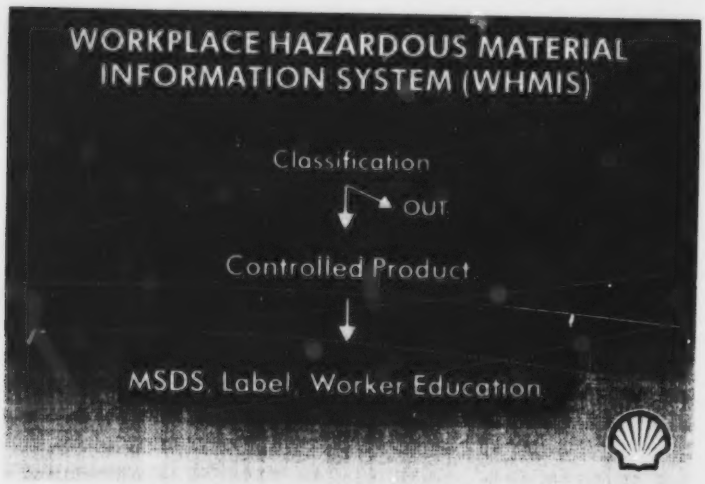
David Bennett, National Representative, Canadian Labour Congress, who represented labour on the WHMIS Steering Committee, was to be here today but is unable to be. He sent CLC's statement on the WHMIS criteria; it is available on the back table.

Criteria Review

Presenter: Geoff Granville
Chairman: Bob Whiting

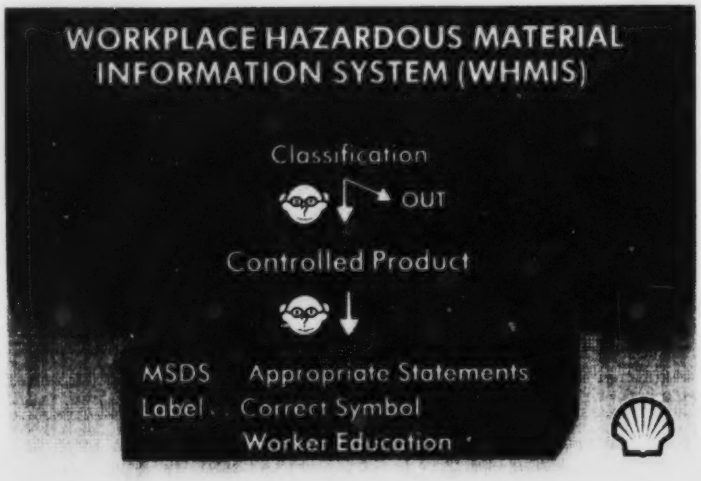
This section is a review on the criteria situation on WHMIS. It's not meant to just go through the criteria; it's going to be an introduction to the whole concept of the need for judgment in WHMIS. The way the criteria were developed was through a long, hard consensus program. They are tough criteria to understand. We believe they can be understood, they can be used and they can turn WHMIS into a good technical piece of information, as well as supply the required communication to the workforce.

Slide 1



In theory, WHMIS is straightforward. As a supplier and as an employer with materials in the workplace, one does a classification. Materials either easily fall out of the classification process or they stay in. If they meet the criteria, you have a controlled product. Based on the identification as a controlled product, the rest of the triad of WHMIS takes place: the MSDS, label and worker education. It sounds so easy, but the more you go into it, the more you realize the complexities. It's important to get the complexities up front so that people can manage the process, and develop a consistent and fair system across Canada.

Slide 2

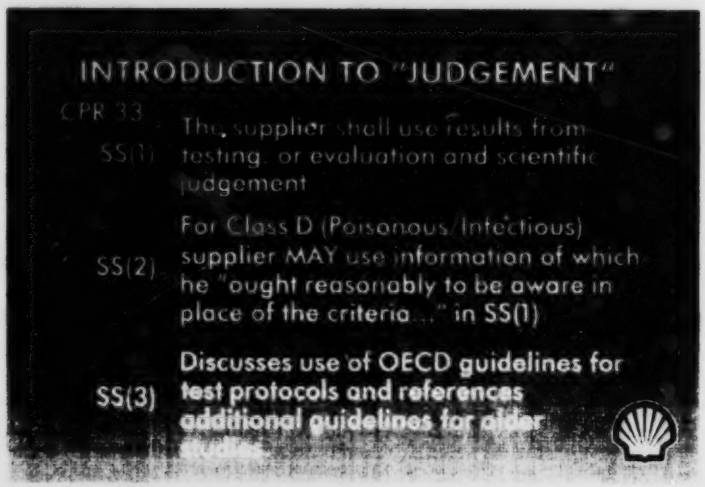


The first area of judgment when going through the classification process is to decide whether a material is or is not controlled. Once it's controlled, another level of judgment is which category or classification that material meets. Based on that judgment, the appropriate statements are important, as is the correct symbol for the label (which is easier than the appropriate statements) and the worker education aspect (probably a location-specific problem). With respect to the statements on the MSDS, depending on the way various information is judged, you may or may not exclude information.

One of the problems of the Canadian WHMIS regulation/legislation is that it's not the same as European or American regulation/legislation, and it's right between the two. In the US, they have a great full disclosure; in Europe, they are the opposite; and Canada is in the middle. The problem is that we're sometimes not too sure how far judgment goes and when it stops, and that creates the hardest situation of them all.

The three areas we will be talking about are: the manner of establishing classification in Controlled Products Regulations 33, a review of the classes of controlled products, and the problems of judgment and the opportunities for doing a good job.

Slide 3


INTRODUCTION TO "JUDGEMENT"
CPR 33
SS(1)
The supplier shall use results from testing, or evaluation and scientific judgement
SS(2)
For Class D (Poisonous/Infectious) supplier MAY use information of which he "ought reasonably to be aware in place of the criteria..." in SS(1)
SS(3)
Discusses use of OECD guidelines for test protocols and references additional guidelines for older studies

CPR 33 is quite an exciting thing. In subsection (1)—the statement says that the supplier shall use results from testing or the supplier shall use evaluation and scientific judgment. It is very hard to mandate judgment. What I would judge as being right is not what someone else would judge—such choices are always different. What we have to try to do is to develop a consistency and an understanding of where we are coming from, a little feeling as to what the regulations are trying to achieve. In that way perhaps we'll minimize problems and disruptions, and maximize the opportunity for fair and good disclosure of occupational hazards in the workplace.

Subsection (2) relates to Class D Poisonous and Infectious Material: the supplier "may use information of which the supplier is aware or ought reasonably to be aware in place of the criteria set out in subsection (1)." In other words, for sections A, B, C, E and F, the supplier shall use results from testing or he shall use evaluation and scientific judgment. For subsection (2) he may use information of which he ought to reasonably be aware. It says what is reasonable—it gives another level of judgment. That's one of the reasons why you have two layers of judgment once you've done your classification and you know you have a controlled product—what information do you need to put in your MSDS? What information should you be aware of?

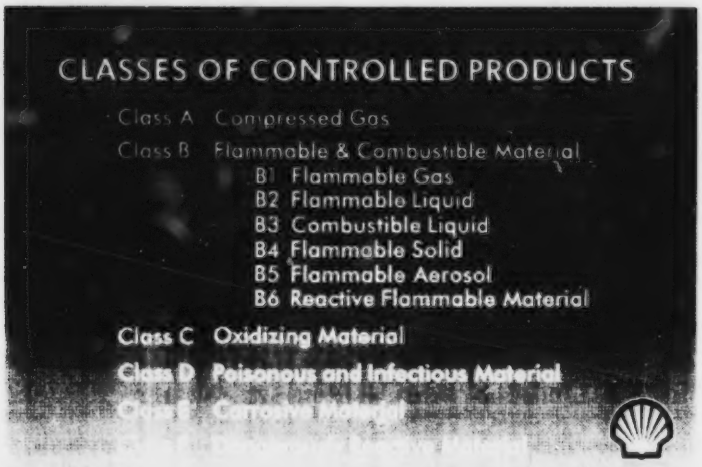
The last section to reference is the use of various test guidelines for acceptable protocols such as the Organisation for Economic Co-operation and Development (OECD) Test Guidelines for any

Geoff Granville *continued*

studies carried out since 1982 when the guidelines were being developed. There are other references for older studies going back to the 1940s such as the Draize Test for skin or eye irritation, and also for studies meeting the World Health Organization criteria. The problem is that these are very dry protocols to go through. It's mandated; you will use them; you have guidelines.

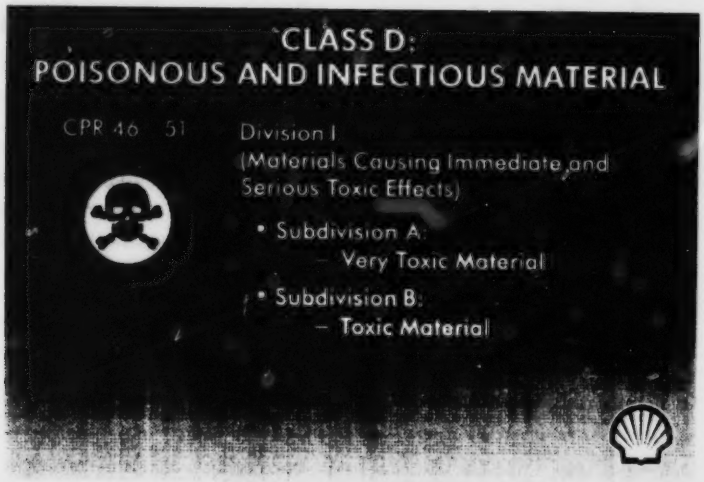
Classes of controlled products

Slide 4



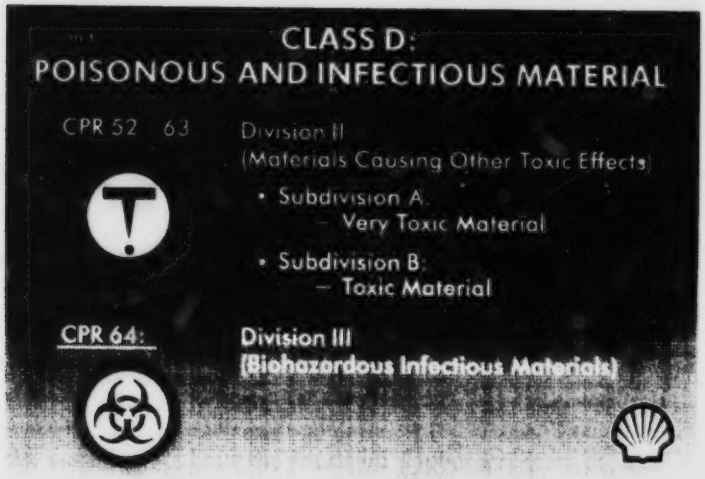
Class A—Compressed Gas is consistent with groups such as Transportation of Dangerous Goods (TDG). Class B—Flammable and Combustible Material is consistent with TDG except for Division 3: Combustible Liquids with a flash point of 37.8° (100°F) or more but less than 93.4°C (200°F). This is important because it means a whole new range of materials will be captured in WHMIS beyond that in TDG. Flammable Solids, Flammable Aerosols and Reactive Flammable Materials make up the rest of Class B. Class C—Oxidizing Material—we'll discuss this one later when we go through one of our materials. Class D—Poisonous and Infectious Material—we'll also discuss this one later. Class E—Corrosive Material—I'll be referencing because it contains some biological requirements. Class F—Dangerously Reactive Material—I will not be addressing again, but it covers materials like 1,3-butadiene.

Slide 5



Class D—CPR 46-51 has three aspects, all relating to Materials Causing Immediate and Serious Toxic Effects: Subdivision A—Very Toxic Material and Subdivision B—Toxic Material, and then two paragraphs dealing with mixtures.

Slide 6



Geoff Granville *continued*

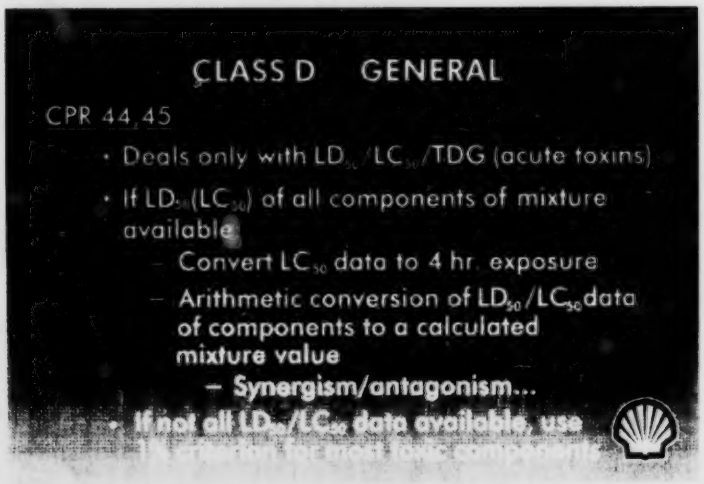
The next major part of CPR goes from 52-63 and it deals with the non-acute hazards which is Division 2: Materials Causing Other Toxic Effects, again, graded in hazard properties between very toxic and toxic materials. Those gradations in both Division 1 and 2 of the subdivisions don't really change a thing for label purposes, but they do when it comes to delivery of hazard information. It's something that allows people in the workplace to focus on Subdivision A—the very toxic category is more of a hazard and something to worry about more than Subdivision B. It's not reflected in the label, but it should be in worker education and workplace matters.

CPR 64 deals with Biohazardous Infectious Material.

I will now go through the acute and other aspects.

The introduction to Class D (and this relates to Division 1, the materials causing immediate and serious effects) deals only with the LD_{50} and LC_{50} matters and the Transportation of Dangerous Goods Act—dealing with the acute toxins.

Slide 7


CLASS D GENERAL
CPR 44,45
• Deals only with LD50/LC50/TDG (acute toxins)
• If LD50 (LC50) of all components of mixture available
– Convert LC50 data to 4 hr. exposure
– Arithmetic conversion of LD50/LC50 data of components to a calculated mixture value
– Synergism/antagonism...
• If not all LD50/LC50 data available, use

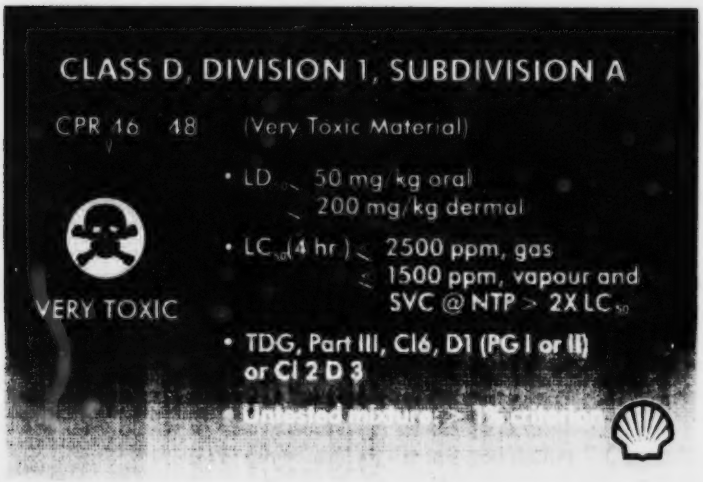
If you have LD_{50} and/or LC_{50} of all components of the mixture, you can calculate a mixture LD_{50} or LC_{50}. This is not a case where judgment is required; if that information is there, you will use the calculation. Note you will also do a conversion of LC_{50}

Geoff Granville *continued*

data to 4-hour exposures. You've got the arithmetic conversion of all the individual data by their reciprocal calculations mentioned to give you that calculated value.

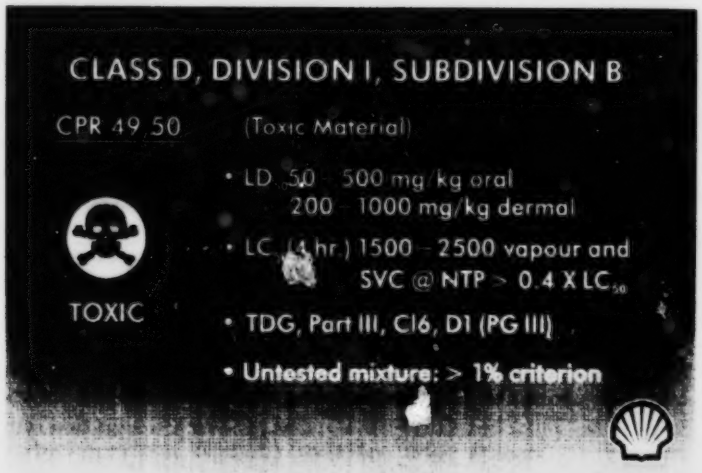
The questions of synergism and antagonism are always mentioned; neither synergism nor antagonism are covered under WHMIS. If people are aware there may be a synergistic effect (and this does happen with acute toxicity from time to time) this fact should be reported. Individual judgment will decide whether there is a problem when working on LD_{50} or LC_{50} mixtures. There is no other way of doing it. If you do not have the LD_{50} and/or LC_{50} data for a mixture, the 1% criteria for mixtures will be used. There is a good chance of nicely over-emphasizing the hazard if you wish to go that way. One can test out the LD_{50} or LC_{50} form which is in the mixture. Otherwise, the facts are given. Apart from the carcinogenicity criteria, this is probably the least judgmental area of the poisonous and infectious class.

Slide 8


CLASS D, DIVISION 1, SUBDIVISION A
CPR 46 48 (Very Toxic Material)
• LD ≤ 50 mg/kg oral
≤ 200 mg/kg dermal
• LC50 (4 hr) ≤ 2500 ppm, gas
≤ 1500 ppm, vapour and
SVC @ NTP > 2X LC50
VERY TOXIC
• TDG, Part III, Cl6, D1 (PG I or II)
or Cl 2 D 3

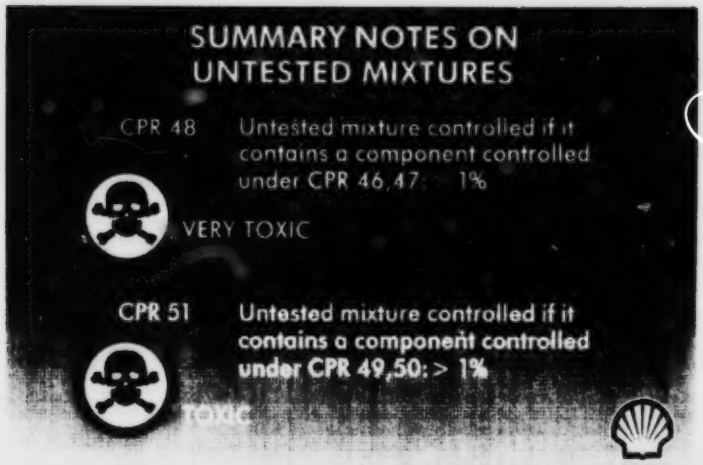
Getting a bit more detailed, CPR 46-48 deals with very toxic material. It references oral and dermal LD_{50} values, LC_{50} values, the complexity about the saturated vapour pressure at normal temperature and pressure, and the reference to the Transportation of Dangerous Goods Regulations. If you have an untested mixture, you apply that 1% criteria. If the material by itself is caught in Class D of Division 1 and is present at 1% or more, the whole mixture ends up being classified.

Slide 9


CLASS D, DIVISION I, SUBDIVISION B
CPR 49,50 (Toxic Material)
• LD 50 - 500 mg/kg oral
200 - 1000 mg/kg dermal
• LC (4 hr.) 1500 - 2500 vapour and
SVC @ NTP > 0.4 X LC50
TOXIC
• TDG, Part III, Cl6, D1 (PG III)
• Untested mixture: > 1% criterion

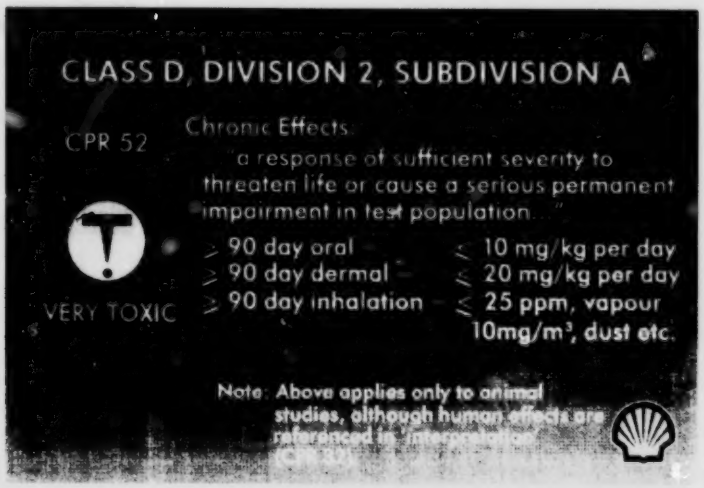
This slide shows Subdivision B of Division 1 of Class D which has similar, yet less stringent criteria than before.

Slide 10


SUMMARY NOTES ON
UNTESTED MIXTURES
CPR 48
Untested mixture controlled if it contains a component controlled under CPR 46,47: 1%
VERY TOXIC
CPR 51
Untested mixture controlled if it contains a component controlled under CPR 49,50: > 1%

In summary, for untested mixtures in both very toxic and toxic parts (Subdivision A and Subdivision B of Division 1), the 1% criteria applies. It is relatively easy to deal with mixtures for acute toxicity.

Slide 11


CLASS D, DIVISION 2, SUBDIVISION A
CPR 52
Chronic Effects:
"a response of sufficient severity to threaten life or cause a serious permanent impairment in test population..."
VERY TOXIC
≥ 90 day oral
≥ 90 day dermal
≥ 90 day inhalation
≤ 10 mg/kg per day
≤ 20 mg/kg per day
≤ 25 ppm, vapour
10mg/m³, dust etc.
Note: Above applies only to animal studies, although human effects are

Things get altogether more exciting when you are dealing with Division 2. CPR 52, Division 2, Chronic Toxic Effects:

> "A pure substance or tested mixture falling into Subdivision A of Division 2 of Class D—Poisonous and Infectious Material, if in an animal assay for chronic toxic effects, it elicits a response of sufficient severity to threaten life or cause serious permanent impairment in a statistically significant proportion of the test population."

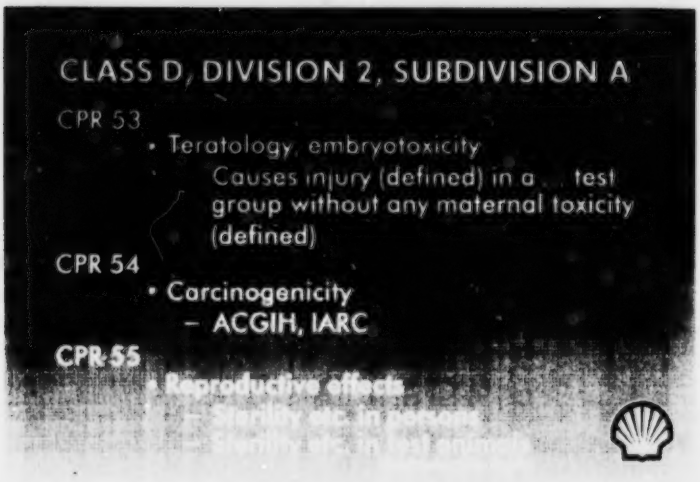
Those words are subject to professional judgment. What is serious permanent impairment? "Life threatening" is straightforward, but "serious permanent impairment" could be a 2% decrement in your vital lung capacity—is that serious? No doubt a 50% to 80% decrement is. Judgment will be needed there.

The last words in the quote are "of the test population." Generally, we are relating this to animal studies, not studies on human beings. The actual quantitative criteria of the 90-day oral, dermal and inhalation studies do give you the actual numbers to work with. If you look at CPR 32 under the definition of chronic toxic effects, human beings are referenced, so there is an inclusion to relate to chronic effects in human beings; it's just that there is no criterion for such effects. That creates problems—it means that everyone will have to decide individually. Will you want to mention, for example, some form of lung disorder in human beings that can result from occupational exposure? They're human effects; they

Geoff Granville *continued*

do happen. Relevant animal models have not yet been developed to actually allow you to predict those things accurately. There is a major potential for error in the practice of professional judgment that is involved in chronic effects. One can say, "there is no mention of animal studies, therefore, I do not have to mention this effect, even though I happen to know it may occur in human beings."

Slide 12



Teratogenicity and embryotoxicity are in a sense more straightforward; what you're talking about is a material that causes injury in a test group of offspring without any maternal toxicity. What we tried to do when this was developed, was to focus on the actual embryo or fetus and not look at any effect that was subsequent or sequential to maternal toxicity. What we couldn't do was put some form of maximum exposure dose in, because some researchers give heroic doses to animals of relatively non-toxic materials which indeed have very minor effects on the mother and also have some effects on the offspring. We will be dealing with one such material this morning. It's quite a problem—we've tried hard to avoid it. There is a certain professional judgment to be practised in teratology.

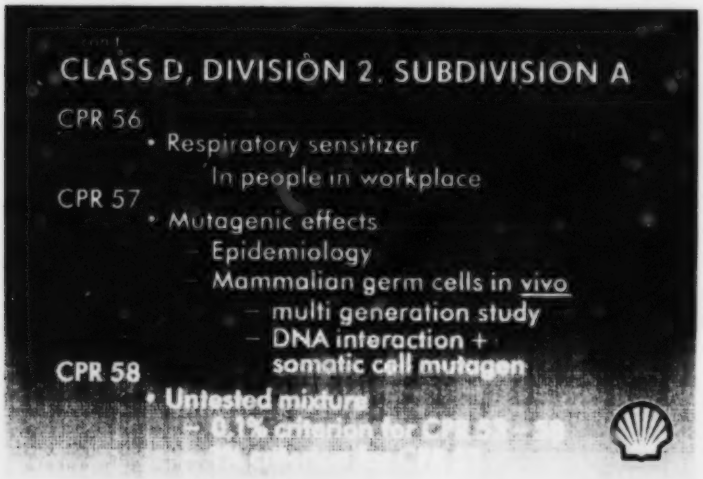
CPR 54—Carcinogenicity is the easiest of the lot. We reference IARC and reference ACGIH, and if it's a carcinogen according to them in Group 1 or Group 2, it's a carcinogen. It gives great

Geoff Granville *continued*

problems to other parts of the community wondering if IARC and ACGIH have done a compatible and fair assessment of the potential carcinogenicity of the materials, but it's not a WHMIS problem. It's a bigger problem than WHMIS in a sense.

Reproductive Toxicity relates to sterility in test animals, referencing OECD guidelines, etc, and sterility in people. Again, you have that question mark; we do not have any mention about exposure or dose. In animals, you have a dose aspect; in human beings, you do not. This could create some problems.

Slide 13



Respiratory Tract Sensitization could be quite a problem because sensitization is a complex phenomenon. People are atypical; there is no such thing as a completely normal human group. The genetic diversity is such that some people somewhere will be sensitive to some materials some time. We know what we're trying to achieve—we're trying to get the materials which really are respiratory sensitizers. What you may be doing, unfortunately, is referencing information that's available in the literature which mentions the odd case. No exposure or dose aspects are referenced in that criterion.

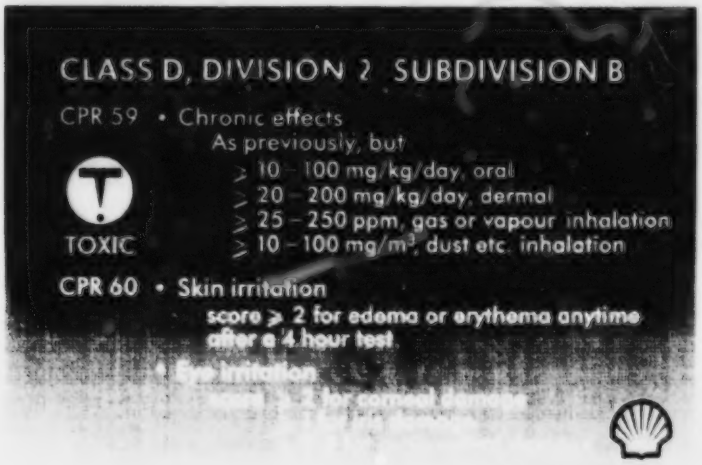
Epidemiology at this time has not shown any human chemical mutagen. The other aspect that CPR 57 deals with is mammalian germ cells in vivo; to demonstrate such an effect, you need either

Geoff Granville *continued*

a multi-generation study (not too many of which are being carried out in this world) or the dual aspect of proof of interaction with DNA in vivo plus a somatic cell mutation in vivo. The mutagenicity aspects are quite complex and tie in with the published National Health and Welfare criteria. These are not going to be easy for most of us to get into and decide whether specific materials are mutagens. There are no other criteria for mutagenicity so we shouldn't be spending too much time agonizing over whether the material is or is not mutagenic.

CPR 58—Untested Mixtures covers any component which is present at a concentration of > 0.1%. This means the mixture will be controlled unless the effect it's brought in for is the chronic toxicity in which case you have that 1% criterion. That's not easy; we'll be doing that many times for 30,000 to 40,000 chemicals in the workplace in this country; it's a big job. It's one of the reasons why we're so concerned about the consistency aspect in application of criteria.

Slide 14


CLASS D, DIVISION 2 SUBDIVISION B
CPR 59 • Chronic effects
As previously, but
≥ 10 – 100 mg/kg/day, oral
≥ 20 – 200 mg/kg/day, dermal
≥ 25 – 250 ppm, gas or vapour inhalation
≥ 10 – 100 mg/m³, dust etc. inhalation
TOXIC
CPR 60 • Skin irritation
score ≥ 2 for edema or erythema anytime after a 4 hour test

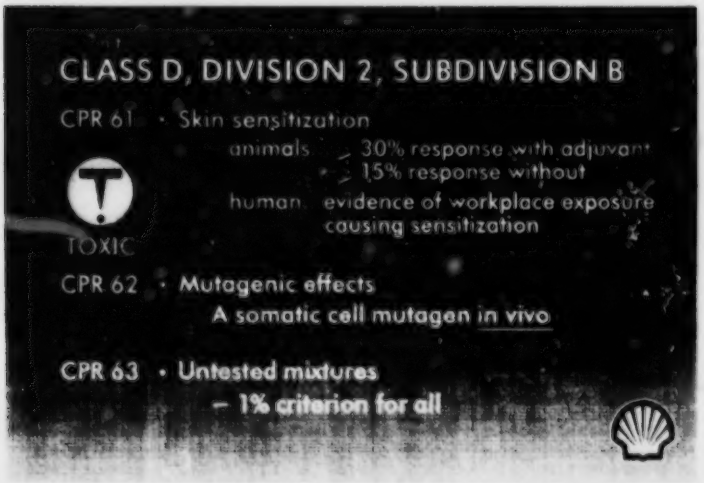
Subdivision B of Division 2—Toxic Material includes the same chronic effects, but at lower concentrations. CPR 60—Skin or Eye Irritation only covers animal studies; there is no input for human skin or human eye irritation. If you have evidence of human irritation, it's irrelevant to the criteria. If you wish to mention it, that's fine. I'm very happy about the inclusion because just about

Geoff Granville *continued*

any material given sufficient contact can cause irritation especially if you test it under occlusion, particularly if you are repeatedly exposed to it week after week, year after year. It doesn't make the material an irritant, it just means that exposure is intensive, and that gives rise to a physiological effect.

The trouble is that these criteria are complex. You can see for skin irritation, you've got that score which relates to the Draize study which was initiated back in 1943, graded at a mean of two or more for either redness or swelling on the skin. When you look at eye irritation, there are other scores which are referenced in that Draize study, such as damage to the cornea, iris and the conjunctiva. Human irritants, skin and eye are excluded from this. What do you do when you know you've got a material which could be an irritant hazard to people and that doesn't have animal data? You use professional judgment!

Slide 15


CLASS D, DIVISION 2, SUBDIVISION B
CPR 61 · Skin sensitization
animals ≥ 30% response with adjuvant
≥ 15% response without
human evidence of workplace exposure causing sensitization
TOXIC
CPR 62 · Mutagenic effects
A somatic cell mutagen in vivo
CPR 63 · Untested mixtures
– 1% criterion for all

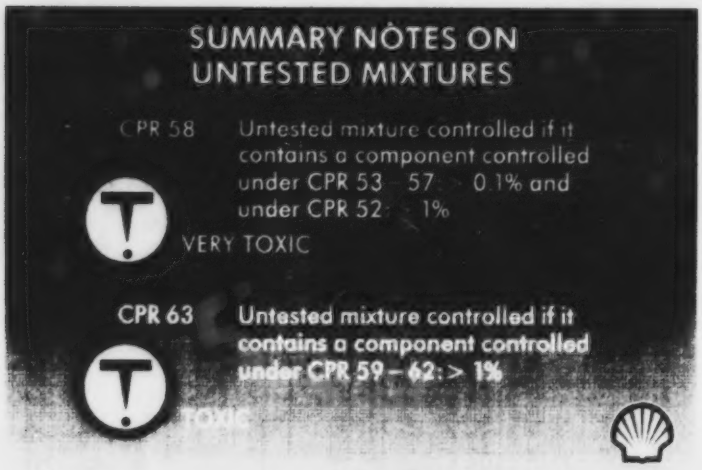
CPR 61—Skin Sensitization can give rise to as many complexities as any, but under WHMIS it's very easy to talk about skin sensitization; you reference the available studies, you talk about the use of an adjuvant, you talk about the 30% response in those studies carried out with an adjuvant and a 15% response without. However, it can be a problem if you're using 10 guinea pigs per study, 1.5 responses are difficult to talk about.

Geoff Granville *continued*

The human aspect is problematic. Even materials such as isopropyl alcohol do have references to being sensitized in human beings. I would submit that isopropyl alcohol (IPA) is one of the safest solvents to use; it's not a skin sensitizer in any animal study and is not in the majority of people. It is used in a variety of medical and cosmetic applications, yet some people have been quoted as being sensitized to IPA. Does this mean you mention IPA as being a skin sensitizer and include it as a toxic material by virtue of skin sensitization? I personally would not. Other people might say, "but there's a referenced article to it"; that's the problem I think we have. I would exclude it and say that on the basis of professional judgment, it is not relevant. I hope that others will come to the same conclusion. I hope that by workshops like this one, we can get to a common status.

The mutagenic effects deal with the somatic cell mutation in vivo which is more of the sort of conventional mutagenicity assays that are carried out. There is an untested mixture criterion which is 1% for any materials captured in Subdivision B of Division 2 which is more than 1% in a mixture, which means that mixture gets classified as Division 2, Subdivision B.

Slide 16

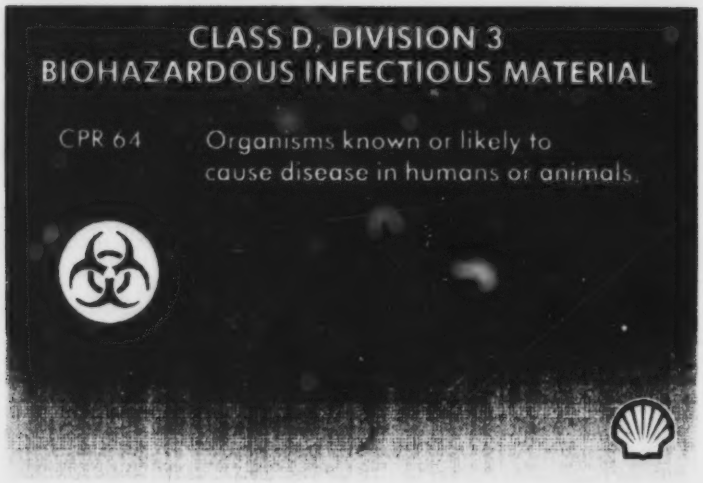

SUMMARY NOTES ON
UNTESTED MIXTURES
CPR 58
Untested mixture controlled if it contains a component controlled under CPR 53 - 57 : 0.1% and under CPR 52 : 1%
VERY TOXIC
CPR 63
Untested mixture controlled if it contains a component controlled under CPR 59 - 62: > 1%

This slide gives the summary notes to untested mixtures for all the previous slides given on Division 2; basically, everything is 0.1% apart from CPR 53-57.

Geoff Granville *continued*

CPR 64—Division 3—Biohazardous Infectious Material

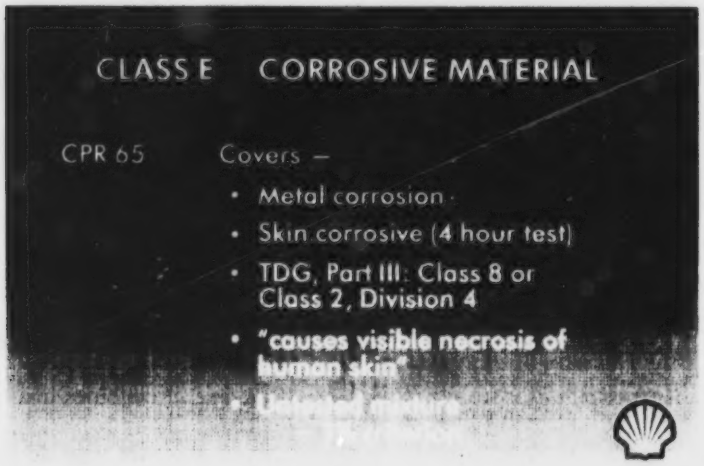
Slide 17


CLASS D, DIVISION 3
BIOHAZARDOUS INFECTIOUS MATERIAL
CPR 64
Organisms known or likely to cause disease in humans or animals.

The final slide before we go more into "judgment" mentions CPR 64. I think we know when we have potential organisms known to cause disease in humans or animals.

The final class is Class E—Corrosive Materials.

Slide 18

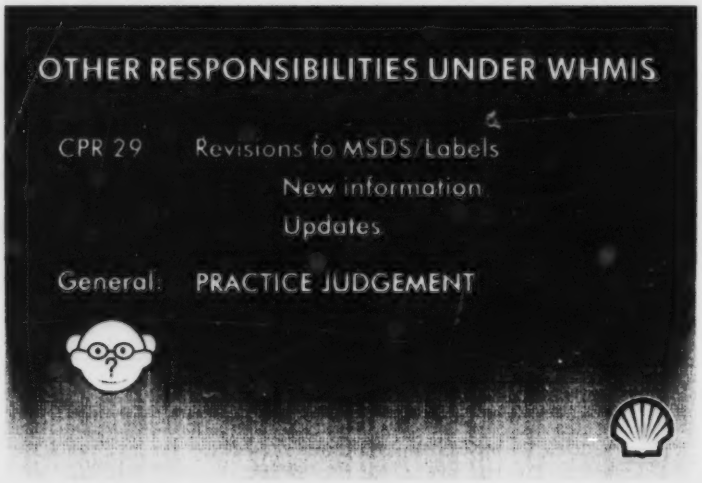

CLASS E CORROSIVE MATERIAL
CPR 65
Covers –
• Metal corrosion
• Skin corrosive (4 hour test)
• TDG, Part III: Class 8 or Class 2, Division 4
• "causes visible necrosis of human skin"

Geoff Granville *continued*

It covers metal corrosion similar to TDG. There is very little debate there. You know just about how much corrosion can be caught in unit time for metals like aluminum. It also mentions an animal study and the skin corrosion test—the 4-hour study. It's quite difficult to define whether you have a corrosive after a 4-hour study. There are some materials which cause just enough irritation that you're not sure whether you've got permanent damage that causes death to the dermis or not. It's easy to reference, but sometimes very difficult to define whether a material is a corrosive. You then have reference to the TDG which makes life easier because you can look at what materials have been previously classified.

The one I have a lot of problems with is the visible necrosis of human skin tissue. For example, if I put soap on my hand for a few hours, am I guaranteed that that will be corrosive by the definition? Is that relevant? Again, we will have problems in expert judgment in talking about visible necrosis to human skin. There is no time scale or exposure factor here, and a 1% criterion for human effects.

Slide 19



CPR 29 talks about revisions to MSDSs and labels. MSDSs will have to be revised every third year and whenever new information becomes available.

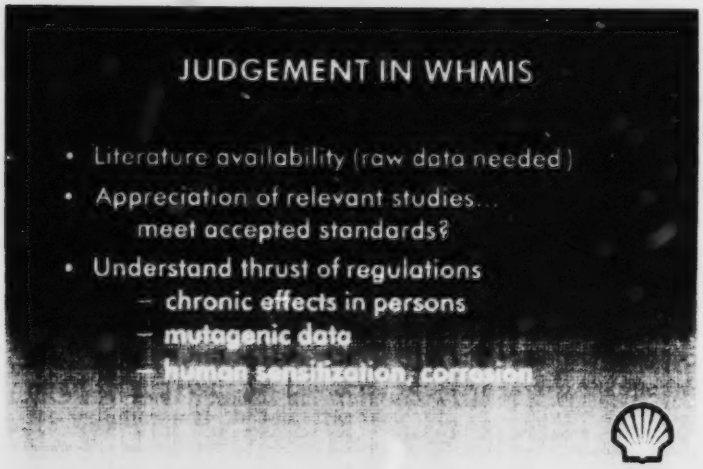
Not only do you have to go through this expert judgment once, you have to go through it every time data become available. How

Geoff Granville *continued*

are you going to check on that data? Are you going to subscribe to fifty-odd journals of toxicology? Are you going to use a clearing house like CCOHS? It's your judgment which will decide what you're going to do when you find significant new information; and it's your judgment whether it's significant enough that you wish to communicate it immediately by updating the labels and the MSDS. It's easy to talk about, but a hard one to practise. I suspect we will be agonizing about this one about a year from now when we finish our first set of MSDS and we begin to look at the literature in slightly different ways. All you can do on this one is to practise judgment. How much time do you have to update your MSDS? That would probably depend on the province when all the osh regulations come out—90 days has been mentioned in some; it may be different in others.

Judgment

Slide 20


JUDGEMENT IN WHMIS
• Literature availability (raw data needed)
• Appreciation of relevant studies...
meet accepted standards?
• Understand thrust of regulations
– chronic effects in persons
– mutagenic data
– human sensitization, corrosion

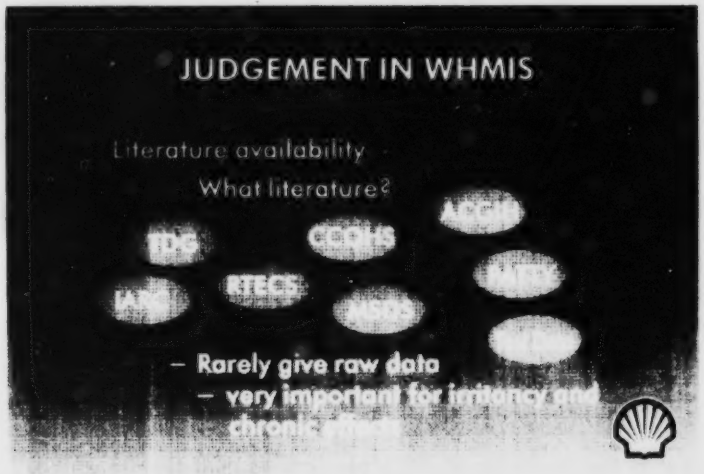
The judgment requirement in WHMIS is present in every aspect—but more so in some than in others. Take literature availability. Large companies and centres like CCOHS can easily subscribe to major literature reviews and can get the current literature. Often what we use are just summaries which come from organizations such as NIOSH and CCOHS—those summaries do not usually have raw data. You don't know whether a skin sensitizer is a skin sensitizer according to the criteria. You don't know things about

Geoff Granville *continued*

the chronic effects—what was the dose that caused that sort of effect—is it life threatening? These are real problems. You're going to have to find the raw data. You're going to have to understand what those relevant studies are about, whether they do or do not meet relevant standards. For example, if you find a study which dates back to 1964, you then have to go back and check on the World Health Organization guidelines, that's a few days' work—even then you're not quite sure.

The one which I think is most important is what I call the thrust of the regulations. What people were trying to do when WHMIS was being developed was to avoid the problem of exposure. Hazard is the result of both toxicity and exposure. If you give massive exposure to people, you're going to have an effect to most materials—that doesn't mean that that material is "more toxic." What we tried to do was to cut out the exposure factor. The way you cut it out is to talk about animal studies and define exposure limits. As soon as you get into the human situation, you cannot do that, yet you cannot ignore human effects in the workplace communication system. We've got a slightly problematic blend of good toxicological science such as exposure levels and the human factors such as the chronic effect in people, the mutagenicity type data, and the human sensitization in corrosion. The criteria don't talk about exposures, but they include exposure in the way that effects have been noticed. Please appreciate that the regulations were not developed to give people a problem, but that will be a major concern. It's going to be a problem of judgment, and I hope we can be practical about doing what is reasonable.

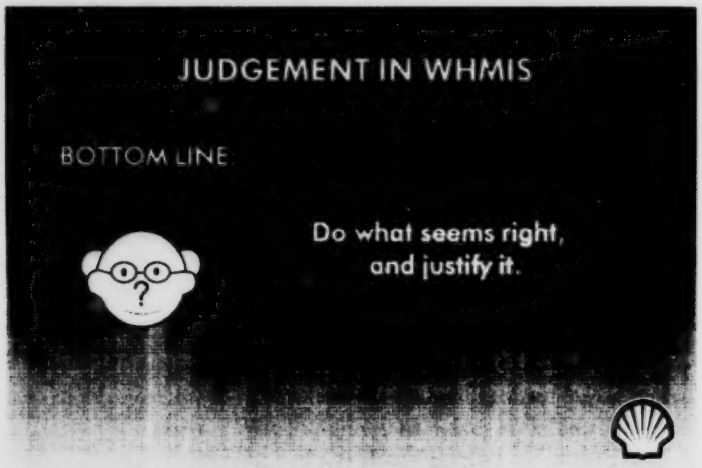
Slide 21



Slide 21 is an expansion on literature availability.

We've referenced 13 major literature sources in WHMIS. The problem is that very few of those give the raw data. IARC does a good job in giving raw data sometimes and gives the justification for its review. TDG has lists; if it's in those lists, you use it; if it's not, you don't. RTECS is a real problem to use; it's non-peer-reviewed and there are a lot of mistakes and errors, yet it's a huge compendium of information. CCOHS does a good job on its summaries. Patty gives very little raw data. ACGIH is a useful text, but doesn't give everything. The MSDSs people will be using are supplied by other people—test data is the one you need most of all. If you don't get raw data, you have problems especially for irritation and chronic effects.

Slide 22



The last slide is what we will be practising; it's what most of the companies I know, which have the resources, will be practising.

I hope I've set the scene for the rest of today. I'm looking forward to this workshop. I hope we have a lot of good interaction. I know the word "judgment" will be used a number of times; it's real, it's critical and it's referenced in the regulations; all of us are going to have to practise it. If we know what other people mean by judgment, I think we'll have a good start towards WHMIS being a valuable tool in occupational health protection in the workplace.

Robert Whiting

Geoff has opened well by emphasizing the role of judgment and experience. One of the aims each presenter has set for himself is, in looking at the classifications of the individual materials that we will be discussing or the criteria or the articles, to sort out from our own experience and judgment how we make these decisions; to compare our experiences and our judgments, so that at the end of the day, we'll have a much better appreciation of what we are trying to accomplish in getting greater consistency in classifying materials under WHMIS.

There will be intensive discussions regarding classifications of individual materials. At this stage, we invite questions and discussion regarding the regulations and their wording to bring out some points that may be applied when we discuss details of some of the materials.

Neil Murray
Imperial Oil

A very basic question, Geoff, that you raise on the use of data. In my reading of the regulations, I seem to have been misguided under CPR 33—Manner of Establishing Classification. Until this point, my reading has told me that for those classifications other than Class D, you have to use test data available or professional judgment—if you did not have that data, you had to get it. For Class D, you will use information which you may be aware of. What I sense from you is that it isn't truly necessary, for example, to do flammable limits or a combustibility test to classify; if something is similar enough, can you use it?

Geoff Granville

That's my reading as well. In CPR 33 (1)(b) where it says, "evaluation and scientific judgment based on test results with respect to: (i) the product, material or substance, or (ii) where appropriate, a product, material or substance that has similar properties." The fact that you can actually relate it to materials with similar properties means professional judgment can be applied. It's up to you to decide just how similar something needs to be to the material you are classifying. I quite agree with you.

Neil Murray

In reading CPR 33 subsection (2): "for the purpose of establishing that a product, material or substance is or is not included in Class D—Poisonous and Infectious Material, the supplier may use information..." It doesn't say "may also use information" but "may use information." I had interpreted it my way—that that was the way you did Class D and for all the others you had to use test data.

Geoff Granville

I think we are in complete agreement, Neil. The word "may" is not the same as the word "must". There's a lot more latitude in this than immediately meets the eye. If you're like me, you spent a lot of time reading that to understand it; I'm still not sure if our interpretation is correct, but that's all you have to go on. There's a lot of professional judgment allowed in CPR 33.

Jim Jernigan
Amoco Corporation

I take it that the 1% cut-off criterion presumed the no-effect level for mixtures at 1%? If we have data on similar mixtures, for example, the no-effect level is at 25%, will we be able to use that as the cut-off?

Geoff Granville

The answer for the 1% no-effect level is that it is incorrect. It's just a number that was thought up, basically to be consistent with the US 1%, but it doesn't imply no-effect level—it may be, it may not be. But you have that 1% cut-off, unless you have your material tested and can prove, for example, that in a binary mixture of 75% and 25% there is no effect from that 25% component of a certain study; if you have not tested that material for that effect, you will have to assume that the 25% material may have an effect, and because it's greater than 1%, you'll have to communicate the hazard. You've always the option to test out, but when you're talking about things such as 90-day studies or carcinogenicity bioassays, it could create quite a problem.

Jim Jernigan

What I had in mind was skin or eye irritation data or carcinogenicity.

Geoff Granville

If you've got skin or eye irritation data and it shows that the 25% component does not have the irritancy that you would otherwise expect of it, then that data should stand—you don't have to communicate the hazard.

Jim Jernigan

We've actually done some studies on human volunteers for skin irritation testing. In some of those cases, materials that appear to be irritants in rabbits, (which appears to have more sensitive skin than humans) turned out to be non-irritating in human tests. In that case, would a human study override the positive animal data?

Geoff Granville

Can we bring that question up after Richard Morris' presentation? I can give you an answer now that animal data is what's specified for the criteria. Your question deserves more of an answer than that.

Louis Hamel
Union Carbide

Nowhere in the OECD Test Guidelines are the species mentioned. Where the data is available, we could have conflicting data from different test species; which one do we use?

Geoff Granville

Some of the OECD Test Guidelines do specify the animals to use, some do not. Again, that's professional judgment. If you think the aardvark is not as relevant as the zebra, you use a zebra. In my opinion, you've got to use professional judgment. If you don't have metabolic data or some other pharmacokinetic to show that one species is better than the other, I'm afraid you should be somewhat conservative and use the animal data which shows more of a hazard, unless you've got good reason to support not using that one. My final slide said, "Use judgment and justify it."

Steven Lerman
Exxon Biomedical Sciences, Inc

For what kind of toxicological end points do you feel you can do the test and negate the necessity of classification? For example, if you test something that contains 0.2% of a carcinogen in an animal study, it's still on the IARC or ACGIH list which means you get negative results. What about some of the other end points?

Geoff Granville

For anything that's included on a list such as carcinogenicity or TDG application, the list takes precedence. You can't test out communication of an IARC or ACGIH carcinogen or a TDG material which is done as a corrosive that you may have tested as showing non-corrosive. For all the others, testing out every time gives you a suitable answer. For example, if you have more than 0.1% of an NTP (National Toxicology Program) carcinogen that is not an IARC or ACGIH carcinogen, you do not have to communicate that hazard unless you wish to. The test data will win out, unless you've got specific lists references.

Steven Lerman

Do you feel that would apply to teratogens and reproductive toxins as well?

Geoff Granville

If you have test data that show it, yes.

Jacques Cerf
Union Carbide

I have a question related to acute toxicity. If in a mixture of three different components, you calculated an LD_{50} and arrived at a number above the criterion, but, you have one component which has an LD_{50} which meets the criteria which is above 1%, how do you classify the mixture?

Geoff Granville

The presence of a component with LD_{50} values that meet the relevant criterion should drive the system.

Jacques Cerf

My second question is, if you had LD_{50}s for three components—one for rats, mice, and polar bears, would you still calculate the LD_{50} for the mixture? Is it scientifically relevant to do that?

Geoff Granville

Had you not said, "Is it scientifically relevant?", I would have just said, yes. Yes, that is what you do, but no, it is not relevant. The drive is to try and classify materials and to try and communicate hazards. No, it's not good science. It's not bad science. It's irrelevant to science—it's a communication vehicle, trying to use information that may be relevant.

Richard Morris

In answer to the previous question regarding the use of the formula, CPR 45 clearly states that, where the ingredients are already over 1%, you can use the formula. The formula overrides the antacid mixture part of the regulations.

Lillian Vine

Over the course of the day I think you will find that the questions are answered or that they generate more questions for discussion.

Classification of Material 1

Presenter: Robert Whiting
Chairman: Peter Robson

It's my privilege to be able to go over the classification of a material which has been very ingeniously designed to bring out points on almost every part of the criteria. You could probably spend all day discussing the classifications of the three ingredients of this material.

The material chosen for this portion of the workshop is a mixture containing 5% maleic anhydride, 20% chloroform, and 75% methyl ethyl ketone. My aim in this section of the workshop is to dig back into my own process of doing the classification, to bring out the kind of information that I had to use and the actual decision-making process. There are many decisions we can make which are based on experience, but a detailed, systematic approach to classification is needed. We must question what we actually know about the material and how it relates to the criteria.

Slide 23

Material 1

	Maleic Anhydride 5%	Chloroform 20%	MEK 75%
A. Compressed Gas	—	—	—
B. Flammable & Combustible	—	—	Flammable Liquid
C. Oxidizing Material	—	—	—
D. Poisonous & Infectious			
1. Immediate	Toxic	Very Toxic	—
2. Other	Very Toxic	Very Toxic	Toxic
E. Corrosive Material	Corrosive	—	—
F. Dangerously Reactive	—	—	

This first slide is a summary of my classification for each of the ingredients. We will go through these materials one by one and discuss how these classifications were derived. Then we can discuss

Robert Whiting *continued*

the overall classification of the material. Some classes we cannot know for sure. For example, methyl ethyl ketone is a flammable liquid, present at 75%, and the product is probably a flammable liquid, but there is no test data on the product.

In other sections, there's less judgment involved. Under Poisonous and Infectious Material—Division 1—Immediate and Serious Toxic Effects, we have very solid data that would indicate a very toxic classification for one ingredient. Under the Poisonous and Infectious Material category—Division 2—Other Toxic Effects, we have very toxic ratings under several categories which would make the product very toxic. Under Class E—Corrosive Material, we have information that would indicate that the product would probably be classified as a corrosive material.

Slide 24

Maleic Anhydride

	Property	Meets Criteria?
A. Compressed Gas	Vapour Pressure 0.00005 mm Hg	No
B. Flammable & Combustible	Flash Point 102° C	No
C. Oxidizing Material	Not Oxygen Donor	No
E. Corrosive Material	Corr. Animal Skin TDG Class 8	Yes
F. Dangerously Reactive Material	Not Violently Self-Reactive, Reaction With Water Gives Maleic Acid. But Violent Decomposition When Heated with 0.1% NaOH	No?

We'll begin with maleic anhydride. Maleic anhydride is not a compressed gas (nor are any of the materials). Materials which are liquids or solids are normally not classified as compressed gases. In some cases, a very volatile liquid might be classified as a compressed gas because the vapour pressure criterion can go up to 55°C. In this case, the vapour pressure (0.0005 mm Hg) is far too low.

Robert Whiting *continued*

The flash point for maleic anhydride at 102°C is just outside the cut-off for the flammable liquid category which is 93°C; it's not a flammable and combustible material though it can burn and it probably would contribute to the flammability of a product. It's obvious that it's not an oxidizing material; it's not an oxygen donor. It needs to be checked to make sure.

The first important decision point is the corrosive material category. Maleic anhydride is definitely Class E—Corrosive Material because it falls into TDG Class 8. It is convenient to be able to use the TDG regulations, because you know right away that a chemical classified in TDG Class 8 must be corrosive material; but it's sometimes rather difficult to actually find the data that this classification is based on. In my review of the information available on this material, I was not able to track much original data on corrosivity.

If you check sources such as Grant's Toxicology of the Eye, which is a good source of information on the effects of chemicals on the eye, or go into NIOSHTIC, which contains extensive information on the toxicity of chemicals, there is very little original test data. You could test the material to find out its pH in solution or whether it is actually corrosive to metal. According to Grant it seems that because maleic anhydride is a reactive material, it is more corrosive than if based strictly on its acidity. So it is classified as a corrosive material.

Another interesting decision point arose in Class F—Dangerously Reactive Material. It would seem at first glance that none of the components in material 1 would be dangerously reactive—and they probably aren't. We found extensive information in the *Kirk-Othmer Encyclopedia of Chemical Technology* on the reactivity of maleic anhydride; I would recommend the Kirk-Othmer Encyclopedia as one of the basic sources of information for the reactive properties of chemicals.

Maleic anhydride is not violently self-reactive; its reaction with water gives maleic acid—these reactions do not seem in either case to meet the criteria.

Maleic anhydride will decompose violently when heated in the presence of trace amounts (0.1%) of sodium hydroxide or other alkalis. This information deserves some discussion because one of the criteria for dangerously reactive material is whether you can get a violent reaction by shock or an increase in temperature.

Robert Whiting *continued*

What is a big enough increase in temperature? Maleic anhydride decomposes at about 150°C which seems rather too high; a temperature increase to 50°C or 80°C in combination with such a tiny amount of contamination could be important. In making a judgment about dangerously reactive materials, you might look at a source such as the *Bretherick Handbook of Reactive Chemical Hazards* to see whether explosions or other reactions have actually occurred in storage facilities or workplace situations. In this case, the information about violent decomposition on heating seems insufficient to make it a dangerously reactive material.

Slide 25

Maleic Anhydride

	Property	Meets Criteria?
D. Poisonous & Infectious		
1. Immediate	LD_{50} (oral g.p.) 390 mg/kg	Toxic
2. Other		
Chronic	Insufficient Data	---
Carcinogenicity	Not Listed	No
Teratogenicity & Embryotoxicity	Insufficient Data	---
Reproductive Toxicity	Insufficient Data	---
Mutagenicity	Insufficient Data	---
Respiratory Sensitization	Human Data	Very Toxic
Skin Sensitization	Human Data	Toxic
Skin Irritation	Severe	Toxic
Eye Irritation	Severe	Toxic

Listed here are the data regarding Class D—Poisonous and Infectious Material. First, there is an LD_{50} in the guinea pig of 390 mg/kg. It is under the cut-off of 500 mg/kg and maleic anhydride should be regarded as toxic under Division 1—Immediate and Serious Toxic Effects. This chemical is not classified as a poisonous material under TDG, but its LD_{50} also meets TDG criteria.

Robert Whiting *continued*

In several areas under Division 2—Other Toxic Effects, there are not enough data to make a judgment. Under categories such as Chronic Health Effects, Teratogenicity and Embryotoxicity, Reproductive Toxicity and Mutagenicity there were no data to indicate whether maleic anhydride would meet those criteria; there isn't much toxicity data on maleic anhydride and, of course, it's not listed as a carcinogen.

The key categories are Respiratory Tract Sensitization and Skin Sensitization. Under these two categories, I was not able to locate the original data on respiratory tract sensitization and skin sensitization. But, in the documentation of TLVs (threshold limit values), a personal communication to the TLV committee indicates that this chemical is a respiratory tract sensitizer and a skin sensitizer; a number of toxicology reviews on maleic anhydride agree. In this case, we simply have to accept their word and say that this chemical is a respiratory tract sensitizer.

The chemical has to be regarded as very toxic because of the consistency of the reports that it is a sensitizer. As additional support for this judgment, other anhydrides are also known as sensitizers; you can be more confident of your judgment if you find that related materials are also regarded as sensitizers. For example, there is more data about phthalic anhydride being a sensitizer than maleic anhydride. Finally, the data on skin irritation and eye irritation seem fairly clear that these chemicals can cause very severe effects on the skin and eyes.

Slide 26

Chloroform

	Properties	Meets Criteria?
A. Compressed Gas	Critical Temperature & Vapour Pressure	No
B. Flammable & Combustible	Not Flammable	No
C. Oxidizing Material	Not Oxygen Donor	No
E. Corrosive Material	Stabilized: Not Corrosive Unstabilized: Corrodes Aluminum	No
F. Dangerously Reactive Material	Stabilized: No Reaction Unstabilized: Yields HCl, Cl_2 Phosgene in Air	No

Robert Whiting *continued*

The second ingredient is chloroform and is present at 20%. Chloroform in one sense is very easy to classify and in another has some tricky points. Chloroform is not a compressed gas; its critical temperature and vapour pressure are outside the limits. Under flammable and combustible material, it has no flash point which can be measured.

In looking at the possible flammability of Material 1, I tried to see if chloroform would act as flame inhibitor; there is not much information about that, although there is an indication in one of the sources that chloroform mixtures with methanol and acetone will burn. In the absence of my actually being able to test the product, that would indicate that Material 1 could be a flammable material. Chloroform is not an oxidizing material.

Class E—Corrosive Material and Class F—Dangerously Reactive Material initially seemed straightforward. Chloroform is not regarded as corrosive or highly reactive. Nevertheless, I did look carefully at whether one could regard chloroform, as well as many other chlorinated materials, as either a corrosive material or a dangerously reactive material. Chloroform requires a stabilizer; virtually all chloroform sold contains a stabilizer such as ethanol. Since ethanol is less hazardous in most of the criteria than is chloroform itself, I did not go through the process of doing the classification of ethanol; although in some other cases, it might be relevant because if there's 2% ethanol in chloroform (and chloroform makes up about 20% of the product) then there's enough ethanol there to be above 0.1% in the final material.

The problem is that unstabilized chloroform can corrode aluminum quite readily. My judgment is that, since chloroform is virtually always used in a stabilized form, you should do a classification on the commercial stabilized material. It would be important to inform workers that chloroform left for a long period in storage might use up the stabilizer and become corrosive; it might also be a good idea not to use aluminum containers for chloroform and for most other chlorinated solvents. I have concluded that it doesn't meet the criteria because it's stabilized.

The same situation occurs in Class F—Dangerously Reactive Material. The stabilization protects chloroform from breaking down and releasing hazardous products. The problem is that among the hazardous products which can be released from chloroform, one is phosgene. The amounts may be small, but if unstabilized chloroform were heated in air, it would give off a toxic gas.

Robert Whiting *continued*

My evaluation was that chloroform as it is commercially sold, is not dangerously reactive, but the user of the material should be aware of what would happen if it were to lose its stabilization.

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Chloroform

	Properties	Meets Criteria?
D. Poisonous & Infectious		
1. Immediate	TDG 6.1 Group II	Very Toxic
2. Other Chronic	Tumours at Doses < 100 mg/kg/day	Toxic
Carcinogenicity	IARC B TLV A	Very Toxic
Teratogenicity & Embryotoxicity	Effects With Maternal Toxicity	No?
Reproductive Toxicity	Effects With Maternal Toxicity	No?
Mutagenicity	Sperm Abnormalities + In Vivo SCEs	Very Toxic
Respiratory Sensitization	Not Reported	No
Skin Sensitization	Insufficient Data	No
Skin Irritation	Mild or None	No
Eye Irritation	Moderate	Toxic

The overall toxicity rating of chloroform relative to both divisions of Class D—Division 1—Immediate and Serious Toxic Effects and/or Division 2—Other Toxic Effects is straightforward; both are very toxic. Chloroform is very toxic in Division 1 because of its listing in TDG Class 6.1, packing group II. It is significant that this rating is not reflected in the LD_{50} or LC_{50} values that would pertain to chloroform under WHMIS. This is presumably a classification based on the extreme hazard of exposure to

Robert Whiting *continued*

chloroform in a spill. Chloroform is automatically a very toxic material under "Other Toxic Effects" because it's in group 2B (probable human carcinogen) of the IARC classification system.

The only chronic data dealing with chloroform are the carcinogenicity studies. For chemicals which are not on the IARC or ACGIH lists (for example, NTP carcinogens), it may be relevant to look at a carcinogenicity study and to make an evaluation based on the doses which were used in those studies. A number of animal studies have shown that doses below 100 mg/kg/day caused tumours and it seems that they would meet the criteria for chronic toxic level.

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Chloroform
Reproductive Effects

	Schwetz et al RAT			Murray et all MOUSE		
Conc. (ppm)	**30**	**100**	**300**	**100**		
				Days 1-7	**6-15**	**8-15**
Fetal Resorption	–	–	+	+	–	–
Retarded Development	+	+	+	+	+	+
Decreased Size	+	–	+	+		+
Teratogenicity	–	+	NS	–	–	W
Anomalies	–	+	NS	–	–	+
Maternal Toxicity						
Decreased Weight Gain	W	+	+	+	NS	+
Decreased Conception	–	–	+	+	+	–
Increased Liver Weight					+	

Information on Teratogenicity and Embryotoxicity and Reproductive Toxicity are very complicated for chloroform. The problem is whether the effects are seen in the absence of maternal toxicity and what kind of maternal toxicity is important? To illustrate this problem, I've laid out some of the results of two animal studies.

The study by Murray looked at the effects of exposure at various times during pregnancy. The other study looked at the effects of various doses over a specific period (Days 6 through 15) in the

Robert Whiting *continued*

rat. In both these studies several very strong toxic effects were observed in the offspring. In both studies there was fetal resorption, retarded development and decreased size of offspring. There was evidence of teratogenicity in the rat study and weak evidence in the mouse study. There was fairly strong evidence of structural anomalies such as rib abnormalities and a few cases of missing tails—some things which are not life-threatening, but are abnormal.

There was evidence of significant maternal toxicity in both studies. The only kind of maternal toxicity that was tested was reduced weight gain and it was seen in both studies. The fact that there was significantly decreased weight gain in the maternal animals would rule out the relevance of these for classification purposes. In some cases, liver changes were also looked at and signs of significant liver injury were seen.

If a study is done well, according to the OECD guidelines, even at the highest dose used there ought not to be any serious toxic effects in the mother. Effects at several doses or times are important in establishing causality. Every part of both studies had at least some maternal toxicity. At best, we have a situation where we have limited evidence that chloroform has embryotoxic and teratogenic effects.

Initially, I was inclined to rate this as a reproductive effect, based on descriptions of the studies in some of the references. Review sources often neglect to mention maternal toxicity. Examination of the original study was essential.

This brings up the question of using information directly from sources such as RTECS data books. You might decide that if someone, presumably reliable, has evaluated a chemical as a teratogen, so can you. The result may often be overclassification.

These studies also showed a reproductive effect on the parent, that is, decreased conception; the animals were mated but an embryo did not form. Decreased conception in the absence of maternal toxicity, would meet criteria in the category of reproductive toxicity. So under reproductive toxicity, I also said no, but with a question mark.

Concerning mutagenicity, a recent paper in NIOSHTIC showed, in a study related to anesthetics, that chloroform would cause sperm abnormalities in mice at doses which were not life threatening.

Robert Whiting *continued*

There was also a paper which showed that chloroform caused sister-chromatid exchanges (SCEs) in vivo. These two studies combined meet the criteria for mutagenicity—very toxic—which requires evidence of an in vivo study showing damage to germ cells and another study showing damage to somatic cells. According to the Health and Welfare guidelines, sister-chromatid data in vivo is acceptable. This is another way in which chloroform becomes very toxic.

The last few categories are simpler. Respiratory sensitization hasn't been reported; therefore, it doesn't meet criteria. Skin sensitization hasn't been reported either. The criteria for skin sensitization allow both animal and human data, but neither is available. I could find no original data on skin irritation; several sources say it's mildly or non-irritating; so it seems not to meet the criteria. Grant and other sources indicate that eye contact is painful and irritating, more or less in the moderate category, so we'd rate that as toxic.

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Methyl Ethyl Keton

	Properties	Meets Criteria?
A. Compressed Gas	Vapour Pressure	No
B. Flammable & Combustible	Flash Point -6° C	Flammable Liquid
C. Oxidizing Material	Not Oxygen Donor	No
E. Corrosive Material	Not Corrosive	No
F. Dangerously Reactive	Stable	No

Methyl ethyl ketone should be the simplest to classify because it's relatively stable and non-reactive. Under compressed gas, the vapour pressure is too low. It is not an oxidizing material. It is not corrosive to skin. The irritation data indicate that it's not corrosive and that it's relatively stable. The flash point of -6°C would put it in the flammable liquid class and, in fact, that low flash point would probably mean that even in the presence of chloroform and maleic anhydride, the product is probably a flammable liquid.

Robert Whiting *continued*

Slide 30

Methyl Ethyl Ketone		
	Properties	**Meets Criteria?**
D. Poisonous & Infectious		
1. Immediate	LD_{50}, LC_{50} Above Cutoffs	No
2. Other Chronic	Above Cutoffs	No
Carcinogenicity	Not Listed	No
Teratogenicity & Embryotoxicity	Effects With Maternal Toxicity	No?
Reproductive Toxicity	Limited Neg. Data	No
Mutagenicity	No Animal Data	No
Respiratory Sensitization	Not Reported	No
Skin Sensitization	Not Reported	No
Skin Irritation	Probably Not Irritating	No?
Eye Irritation	Moderate to Severe	Toxic

In Class D—Division 1, it was fairly clear that the LD_{50} and the LC_{50} values were above the cut-offs; it would not be immediately toxic. In Division 2, the chronic data available is also well above the cut-offs. It is not listed as a carcinogen. Teratogenicity and embryotoxicity is a problem as we will see in a moment. The only thing we found that definitely brings methyl ethyl ketone into Class D is eye irritation.

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Methyl Ethyl Ketone
Reproductive Effects

	Schwetz et al 1974		Deacon et all 1981	
Conc. (ppm)	**1000**	**3000**	**1000**	**3000**
Embryo Toxicity	-	+	-	-
Fetotoxicity (Abnormalities)	+	+	-	W
Teratogenicity	-	W	-	-
Maternal Toxicity				
Decreased Weight Gain	-	-	-	+
Liver Changes	-	-	-	-
Decreased Implantation	-	-	-	-

If methyl ethyl ketone had reproductive effects, it would be very toxic and much more worrisome. The study by Schwetz et al, 1974, found that methyl ethyl ketone at 3,000 ppm (parts per million), 7 hours/day on days 6-15 of gestation in rats was embryotoxic, fetotoxic and somewhat teratogenic in the absence of maternal toxicity. Based on that study alone, you'd have to conclude that methyl ethyl ketone was a very toxic material.

A second study done by some of the same investigators was designed to check in more detail whether this first study was correct. The second study used larger numbers of animals, more detailed analysis and more control over exposures. This study found that methyl ethyl ketone was not embryotoxic, not teratogenic, had a mild fetotoxic effect and that there was maternal toxicity in the form of decreased weight gain.

The second study may well be more reliable than the first. Given conflicting information, you cannot conclude that methyl ethyl ketone is an embryotoxin or a fetotoxin. Nevertheless you would have to communicate that these studies existed and found reproductive effects in the presence of maternal toxicity. As part of the study, the effect on pregnancy was looked at; neither study showed any effect on pregnancy. It is clear that there was no reproductive effect on the parent.

There is no data on mutagenicity. Respiratory sensitization was not reported. There is no data on skin sensitization in animals or humans.

Robert Whiting *continued*

The information on skin irritation illustrates a serious difficulty in classification. In RTECS, there is a citation that methyl ethyl ketone is a severe skin irritant. If you examine the actual paper, you will find that it was an interlaboratory comparison of results from 25 laboratories testing 20 different chemicals to see how consistent skin irritation and eye irritation data were. In the Draize-type test, methyl ethyl ketone was applied to the skin for 24 hours; the skin was then studied over a period of weeks. Twelve out of the 16 laboratories in the study found that methyl ethyl ketone was not irritating; the other four found that it was. One or two of them rated it as severely irritating, which is where the citation in RTECS came from. RTECS took the worst result reported among all of the studies done.

It was interesting to note that following the initial study, methyl ethyl ketone was retested in several of the laboratories under the watchful eyes of one of the authors of the paper. When he was there to watch the studies, the labs reporting the non-irritating result still found it non-irritating, but the labs that rated it as highly irritating came down considerably. Virtually all of the results were in the non-irritating category. Obviously, it is best to look at the original paper; in some cases, you don't have that option because the chemical has only been tested once and you have to accept what was done. That is a problem—it may mean that the results from one company to another or one agency to another may legitimately be different.

Eye irritation is fairly straightforward—methyl ethyl ketone is moderately to severely irritating.

We've gone through the classification of maleic anhydride, chloroform and methyl ethyl ketone and come up with the individual ratings of those materials. What would the overall rating of the product be? Probably it is a flammable liquid and rated very toxic under both divisions of Class D. The product would probably be corrosive if tested in animals because of the strong effects of maleic anhydride. The dangerously reactive material category, we can't be sure of. It was fortunate that we used an acid rather than a base because chloroform, methyl ethyl ketone and bases together form a dangerously unstable mixture. I'm not sure what happens with an acid—it may not be quite so dangerous, but it would seem that it's not a dangerously reactive material.

Lillian Vine

We had originally thought each panelist might classify the same material and speak of the process he would have used and his results; but we thought that might prove repetitious. Instead, Bob Whiting and Marc Baril each prepared classifications of one material. The other panelists also gave it thought. Each panelist might have used different processes and/or reached different conclusions. You will now hear from them. There may be points of disagreement or they may have all come to the same conclusions. We then invite you to contribute input and discussion.

Marc Baril

For the most part, we arrived at the same conclusion as Bob did. Our main problem was embryotoxicity. It took us two or three weeks just to get the article by Murray; the literature is very scarce on these specific matters.

David Gaylor

The reproductive effects summary was excellent. In the last case, the skin irritancy conclusions demonstrated the importance of going back to the original paper. We reached the same conclusion as Bob did. I have a few questions. Why did you quote the LD_{50} for maleic anhydride from a guinea pig where there was oral rat LD_{50} data available (although the same conclusions were reached)? Mutagenicity of chloroform—I didn't find the same data as you did, but obviously you did a much more thorough search. With respect to the LD_{50}s, there were LD_{50} data for all three components and we didn't do a calculation, but we didn't really have to, I guess.

Robert Whiting

In the case of the LD_{50} data, it was fairly obvious that the calculation would put it out because the numbers for chloroform and methyl ethyl ketone are above the cut-off of 500 mg/kg. With maleic anhydride there was a value of 390 mg/kg for guinea pig, and I think there was also another value under 500 mg/kg for rat or mouse. In general, it's better to quote rat or mouse LD_{50} values than guinea pig because there can be a great deal of variation from species to species. You're not held to a particular species in the OECD Test Guidelines, so you have to make a judgment based on whether guinea pigs or any other species are relevant to human exposure.

Robert Whiting *continued*

In doing these literature searches, our major source of data was NIOSHTIC. The problem with methyl ethyl ketone and chloroform is the number of citations. NIOSHTIC has about 500 citations on each of them. It's important to adopt strategies to decide what kind of data you need. For example, if it's mutagenicity, which became an issue with chloroform, it's important to use the search terms that will bring out information on mutagenicity apart from everything else. Instead of sorting through 600 papers on chloroform to find the mutagenicity data, use a few combining terms to get it down to about 10.

Another point about chloroform mutagenicity is that if you look in almost any data book—IARC monographs or any of the others, the in vivo studies are not referenced; I'm not sure why—maybe because they were done for other purposes. The chloroform study was done from the point of view of anesthesiology and the SCE study from the point of view of contaminants that may form in drinking water.

Peter Robson

This was an extremely thorough piece of work, Bob. One thing I would question is the mutagenicity of chloroform. I can recall when these criteria were developed after a lot of discussion; it was the overall impression that it would be a rare event when we came across a mutagen that would meet the very toxic criteria, and here we have one. I certainly did not find this information in the limited search I did. I just pulled out the criteria and read them, and I still find it questionable whether the description that you gave about the sperm abnormalities really meets the criteria.

Robert Whiting

I went through the same decision process myself because the criteria are not very definite about what is to be considered in terms of chromosome abnormalities, damage to germ cells or DNA damage in vivo. I turned to the Health and Welfare guidelines which give a lot of latitude. For example, initially, I did not think that a sister-chromatid exchange (SCE) experiment in vivo qualified as gene mutation in somatic cells; but the Health and Welfare guidelines say that there are no good tests in vivo for gene mutation and that in the absence of such tests, one shall use indicator tests such as sister-chromatid exchange. You must check exactly what these various guidelines say is acceptable.

Richard Morris

I look at classification in two ways. When you arrive at the end-point, will you label it correctly? If so, are you going to give it the right label? Regardless of how we would have dealt with the individual criteria, in the end we probably ended up with the same results. Given a wide range of chemicals, there's a possibility that if you missed one thing, you may pick it up somewhere else under another criterion.

This example did highlight the need for professional judgment we want to emphasize. The criterion may be fairly explicit and fairly clear in some cases, but you may still have trouble getting to the point of being able to use the criteria. A case in point are the teratogenicity studies; I tend to agree with Bob in his interpretation of those studies. If you choose not to use those studies, it doesn't affect the final result. In a case where it knocks it from very toxic to toxic because, for whatever reason, you decide not to use the study, you have to be really careful about that judgment.

The sensitization data for maleic anhydride are very weak and not very well verified. I would want to see much better evidence. Again it doesn't affect the final outcome of this classification.

I agree with Bob's interpretation on chloroform. For methyl ethyl ketone, one good negative study may very well override a poorly-conducted positive study. One might still mention in the MSDS that there is a positive study, but that you're not satisfied with the way in which it was conducted. It says in the regulations that you mustn't put in disclaimers. For example, if you have a positive study, you mustn't say there is a positive study, but you don't agree with it. You can justify why you've chosen to ignore it (because there's a better negative study available). You're not meant to disclaim the legitimacy of a positive result. One thing one could have used for the acute lethality, although this wouldn't have had an effect on the outcome, was the product LD_{50} value. It would have knocked it out on the acute lethality basis.

Geoff Granville

I have comments on Bob's approach and review. For maleic anhydride you can use professional judgment from other anhydrides. I have problems with the human sensitization data, but we know that other anhydrides are good respiratory and skin sensitizers, and I think that one would build that into the process.

I have slight difficulty with your classification of chloroform under Class D—Chronic Health Effects because I look at tumors as being

Geoff Granville *continued*

a carcinogenic response rather than a chronic response. Because it's captured in the form of an IARC carcinogen, you could ignore the chronic effects; but I see you using a different logic pathway.

Robert Whiting

My approach was to try to find any data under each category. For a recognized carcinogen such as chloroform, using the carcinogenicity data under chronic effects is not necessary. In the case where you might have an inconclusive carcinogenicity study or a positive study for an NTP carcinogen, you could take that data into account. There's one OECD Test Guideline which combines carcinogenicity and chronic toxicity studies; that would be a very useful kind of study to obtain if it's available.

Geoff Granville

A point is on methyl ethyl ketone and the teratology aspect. We all independently came to the same conclusion that methyl ethyl ketone is not a practical teratogen; we would make our own decision whether to classify bases and how we would communicate it. In view of the doses in the methyl ethyl ketone study, which was half of the LC_{50} concentration, I'm glad to see that we all independently came to the same conclusion; this is justifiable science rather than over-disclosure of the relevant information.

Roman Kostiuk
Hoechst Canada Inc

It is easy to find references on the three ingredients of the product if you do a literature search, but what if there were a fourth ingredient in that controlled product and that ingredient happened to be a pigment for which no data is available? What do you do in a situation like that? Do you disclose it as a hazardous ingredient since no toxicity data are available? You don't know whether that pigment is a mutagen, teratogen, you don't know its oral toxicity values...

Robert Whiting

You have little choice other than to say that, for this ingredient, there is no data available. You could evaluate the general toxicity of the chemical family, but in classification, it's difficult. Unless you could make some sort of extrapolation which you could justify, you would not need to classify it.

Roman Kostiuk

If you have a feeling that that pigment would not cause any toxic effect, there's no need for you to classify that pigment?

For example, if that mixture is a paint formulation, you would classify that mixture according to flammability because of the solvents and you'd have a flammable label, but that label would not be referring to that pigment which is also on the ingredient disclosure section of the MSDS?

Robert Whiting

Probably not. You have to somehow evaluate its toxicity. You have to use the information you've got on the ingredients and on the product. For example, if the product contained an oil and methyl ethyl ketone, and methyl ethyl ketone was an eye irritant but it was present in a low concentration, you could test the product and show whether it actually is an eye irritant. You have to use all the information that's available.

Roman Kostiuk

But if you don't test, you must disclose that on the MSDS? But you don't label it according to a certain hazard symbol, you just go by the other ingredients that are there?

Robert Whiting

Yes.

Peter Robson

I see two processes going on here: classification and MSDS disclosure. They are separate. First, you apply the classification rules. When you come to this pigment ingredient, there is no information. The basis for classification is that you shall use the available data; you are not required to test. That was the basic premise for toxicity in the classification for WHMIS. The properties of the other components of the mixture classify it so it's brought into the WHMIS system and an MSDS is required. The presence of the pigment is not reflected in the classification, but the presence of the pigment is identified on the MSDS because the disclosure rule requires it to be there. In the health hazard information, you would simply say: no information is available on this ingredient.

Jacques Cerf
Union Carbide

The amount of work required to classify products is well demonstrated by this example. Wouldn't it be a good project for CCOHS to get involved in classifying basic commodity chemicals? What I would suggest as a start might be the chemicals from the Ingredient Disclosure List.

Robert Whiting

We are doing that as part of our building of CHEMINFO records. It is a major undertaking to carefully review and classify each material. We are classifying the materials which we are most often asked about. It is going to take time to do all of the chemicals on the Ingredient Disclosure List. We are also interested in comparing the results of classification by different organizations and getting feedback so that we can expand the classifications in CHEMINFO and refine our procedures. If another classification is different, what information or interpretation of data is available that might change our opinion? The information that's given under the classification of the various chemicals in CHEMINFO should represent the best scientific consensus available.

Jacques Cerf

How long did it take you to classify this mixture?

Robert Whiting

In this case, it took about a week; that's because of the intensity of trying to find every bit of information that was relevant to every one of the criteria for this chemical. The classification process could take an hour or it could take a week; it depends how much you rely on other people's opinions, other evaluations in books and how much data you already have available. There aren't many chemicals that have as much data as chloroform; more often you start with hardly any.

Charles Kennedy
Canadair Ltd

At the workplace, we need to know the toxicity of many products because we sometimes work with as many as 60, 100 or 1,000 chemical products.

Robert Whiting

That's a good point. One of the very few cases where you can demonstrate toxicological synergism is between chlorinated solvents and ketones. A part of the information on the MSDS of this product would be the fact that chlorinated solvents and ketones together may be more toxic than the materials separately. However, information on synergism is rarely available; it can rarely be quantified to use for classification. If you were convinced that the combined effect might be greater, you would use fields such as toxicological synergistic products on the heading of the MSDS to indicate any information you have about drugs or other chemicals in the workplace which may react with that particular product. It's very difficult to incorporate into the classification process.

Myra Plotnick
Monsanto Canada Inc

As a matter of clarification, your product in the end was very toxic—very toxic and flammable. Would the skull and crossbones symbol override the "T" symbol for the classification of the first material or would you have both?

Peter Robson

If we are talking about the application of the symbol on the label, my understanding is that the skull and crossbones applies only to one group—acute lethality, very toxic. It's not used for acute lethality, toxic. If some other criterion is met in the poisonous and infectious material category that would justify the "T", you do not have the two symbols; the skull and crossbones takes precedence.

Myra Plotnick

For example, let's assume that the LD_{50} did not meet the criteria and it was neither a respiratory sensitizer nor a skin sensitizer, and you had on your warning statement, "corrosive to eyes and skin". Would it still require a "T" symbol because it's also an eye irritant once it's corrosive?

Robert Whiting

I believe so. There's a touch of judgment because that's the only category. I think you could justify leaving off that symbol if it was only an eye or skin irritant.

Bruce Koivisto
BDH Chemicals Inc

In terms of classifying the product, you found that it was classified as very toxic because of several different criteria. When you find one that classifies it as very toxic, does this mean you've now classified it? That other information is valuable for preparing the MSDS, but as far as classifying is concerned, you're saying that once you've got one classified, you don't have to keep on finding the others. Also, why didn't you do the calculation of the LD_{50}?

Robert Whiting

I didn't present the calculation because two out of the three values are well above the 500 mg/kg, and the net result would obviously be above the 500 mg/kg.

Bruce Koivisto

CPR 45 of the Act doesn't give you an option; it says: "shall be determined". There's no reference in the Act to where you use that calculated LD_{50}. Where was the information that you used in classifying the product?

Robert Whiting

You use the LD_{50} to classify according to acute lethality. If the product has LD_{50} below 500 mg/kg, then that is used as part of the classification.

Peter Robson

There is no purpose in calculating the LD_{50} or the LC_{50} other than for the classification because that calculation method is embodied in the section that deals with classification.

Bruce Koivisto

Those sections clearly tell you what kind of an LD_{50} you use. It talks about a pure substance or a tested mixture which this isn't—this is an untested mixture. CPR 46 and 49 clearly don't apply. There's nowhere which tells you how to use a calculated LD_{50} or LC_{50}.

Peter Robson

I understand that in the language of the regulations, it doesn't spell it out, but I can tell you that it was the intent that you would use the calculated LD_{50} and LC_{50} for that purpose.

Dennis Driscoll
Amoco Corporation

I'm a little worried as a supplier to hear that it took you about a week to classify that product. How much detail could we be expected to go into if we have several hundred products? What would be the penalty if we missed some information?

Robert Whiting

My understanding of the legal requirement is that you must do a reasonable job of it. There are a lot of books that summarize chloroform toxicity, maleic anhydride toxicity and methyl ethyl ketone toxicity. In many cases, it's adequate to use secondary sources if they're consistent and they seem to make sense relative to the known chemistry of a material; that might take a few hours.

The point in doing this particular material was to examine what information was found in different sources, how the information was found, and what the difficulties were in interpreting it. I spent more time than I would normally spend doing the analysis. If I had spent only a few hours, I would not have found the mutagenicity data in any of the secondary sources. You find it if you do a thorough data base search—it might make a difference.

Even if you missed a certain piece of information, and somebody finds the information in CHEMINFO, you'd be aware of it from that point on.

Lillian Vine

As mentioned at the beginning of the workshop, we will publish the proceedings. They should be available in approximately three months, after it has been reviewed by all the panelists. The French translation will follow shortly after.

Application of criteria for skin & eye irritation

Presenter: Richard Morris
Chairman: Geoff Granville

I am here today not as a representative of Health & Welfare Canada, but as a toxicologist who has been involved in WHMIS for a long time. Even though I'll be going into some detail about testing methods in the area of skin and eye irritation, these are not mandated tests.

I was asked to look at skin and eye irritation. It is only one small part of the WHMIS criteria, but it does bring up a lot of the elements we've discussed today, such as scientific or professional judgment and the availability of test data. I will begin by briefly discussing some of the aspects that relate to classification such as trying to differentiate between three different end points that are often confused.

Slide 32

IRRITATION (PRIMARY)	CORROSION	SENSITIZATION
LOCALIZED NON-ALLERGIC (PHYSIOLOGICAL) RESPONSE	LOCALIZED CHEMICAL REACTION	LOCALIZED AND SYSTEMIC ALLERGIC (PHYSIOLOGICAL) RESPONSE
RESPONSE GENERALLY IMMEDIATE, OCCURS ON FIRST EXPOSURE	ACTION MAY BE IMMEDIATE OR DELAYED	ALWAYS REQUIRES PRIOR EXPOSURE
RESPONSE GENERALLY DOSE/ CONCENTRATION RELATED	ACTION MAY BE DOSE/ CONCENTRATION RELATED	LITTLE OR NO RELATIONSHIP BETWEEN DOSE/CONCENTRATION AND SEVERITY OF RESPONSE
EFFECTS GENERALLY DISAPPEAR WHEN CHEMICAL REMOVED	TISSUE CHANGES GENERALLY IRREVERSIBLE	EFFECTS MAY GRADUALLY DISAPPEAR IF SENSITIZER REMOVED
SOME INTER-SPECIFIC AND INDIVIDUAL DIFFERENCES IN RESPONSE	NO STRIKING INDIVIDUAL OR INTERSPECIFIC DIFFERENCES	STRIKING INDIVIDUAL AND INTER-SPECIFIC DIFFERENCES

Chemicals can be classified as one or the other of these three, although some may fall in more than one group. It depends on the dose or concentration of the material and the duration of the exposure. Some useful generalizations can be made to differentiate these from the point of view of our discussion today.

The first area I'd like to deal with is whether the particular effect is toxicological, physiological or chemical. Primary irritation is a localized non-allergenic response. Corrosion is a localized

Richard Morris *continued*

chemical reaction. Since it is a chemical reaction, it isn't necessary to use a live animal or live animal tissue to confirm the effect. For example, it would be easily demonstrated in an eye from an abattoir. It isn't included in the OECD Test Guidelines, but it could be an alternative approach to be considered in the future.

In the case of irritation, the effect is generally immediate. Related to the definition of primary irritation, it usually occurs on the first exposure. In the case of corrosion, the effects are also generally immediate, but there are examples of a delayed effect. It almost always relates to the nature of the chemical reaction. (For example, if the chemical reaction is slow, or if the material must be absorbed through layers of tissue to reach a specific layer to have its effect or in the case of an alkylation reaction where corrosion effects are "downstream" from the immediate chemical reaction.) Sensitization always requires—by definition—a prior exposure and, in some cases, several previous exposures.

Irritation as a physiological or toxicological response is generally dose-related. Corrosion may be dose-related depending on the range of concentration. Once you reach the point where the damage is occurring, any increases will perhaps only speed up the reaction. Sensitization, in many cases where it has been studied, shows little or no relationship between the dose and the severity of the effect. Often it occurs at relatively low doses. In some cases, there may be some relationship between dose or concentration and the initiation of sensitization.

What happens when the material is finally removed from the tissue? You can also find some differences. In the case of an irritation, normally when you take the material away, the effects of the irritation and inflammation should disappear. Corrosion is normally thought of as an irreversible effect, but the tissue changes may undergo some healing with time. The damage has been done and the repaired tissue would probably not be the same as the original tissue—it would be recognizable as scar tissue. The effect of sensitization, like irritation, may gradually disappear depending on the nature of the sensitization.

There are some interspecific and individual differences in response to irritation in different animals. In the case of corrosion, you don't expect any marked differences. With sensitization, we find striking differences between individuals and species in their response. The guinea pig is used in many cases because it's more sensitive than most other laboratory animals. One of the problems with dealing

Richard Morris *continued*

with sensitization on a MSDS is that there might be a case where only one worker of many who have been exposed to something has developed some sort of reaction. Does that mean the material in question is a sensitizer? In the case of respiratory sensitizers, the outcome can lead to a fatality and it has to be dealt with on a very serious basis. In the case of skin sensitization, the judgment is a little easier to make because the outcome is not nearly so serious.

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20/1/88 *Canada Gazette Part II, Vol. 122, No. 2*

Registration
SOR/88-66 31 December, 1987

HAZARDOUS PRODUCTS ACT

Controlled Products Regulations

P.C. 1987-2721 31 December, 1987

REGULATIONS RESPECTING CONTROLLED PRODUCTS

Manner of Establishing Classification

33. (1) For the purpose of establishing that a product, material or substance is included in a class listed in Schedule II of the Act or falls into a division of a class, the supplier shall use, subject to subsection (2),

(*a*) results from testing that he has carried out

(*b*) evaluation and scientific judgment based on test results

(3) Where the test results referred to in paragraph (1)(*b*) are results from toxicological studies, the studies shall have been carried out in accordance with

(*a*) the applicable OECD Test Guideline referred to in this Part; and

(*b*) where there are no tests carried out in accordance with the applicable OECD Test Guidelines referred to in this Part, one of the following tests or methods:

(ii) in the case of a test for skin or eye irritation, the Draize Test as described in volume 82 of *The Journal of Pharmacology and Experimental Therapeutics*, dated 1944, at pages 377 to 390.

(v) any other test or method that is carried out in accordance with generally accepted standards of good scientific practice at the time the test is carried out.

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continued

Skin or Eye Irritation

60. A pure substance or tested mixture falls into Subdivision B of Division 2 of Class D — Poisonous and Infectious Material if, in an animal assay,

(*a*) it causes an effect graded at a mean of two or more for erythema formation or two or more for edema formation, when tested in accordance with OECD Test Guideline No. 404, "Acute Dermal Irritation/Corrosion", dated May 12, 1981, as measured at any of the times specified in the test; or

(*b*) it causes an effect graded at a mean of two or more for corneal damage, one or more for iris damage or 2.5 or more for conjunctival swelling or redness, when tested in accordance with OECD Test Guideline No. 405, "Acute Eye Irritation/Corrosion", dated May 12, 1981, as measured at any of the times specified in the test.

Untested Mixtures

63. An untested mixture falls into Subdivision B of Division 2 of Class D—Poisonous and Infectious Material if it contains a product, material or substance that meets any of the criteria applicable to a pure substance or tested mixture referred to in any of sections 59 to 62 and is present at a concentration of one per cent or more.

I'd like to direct your attention to an abridged copy of the Controlled Products Regulation's (CPR) criteria that are important for us in discussing the classification of skin and eye irritants. Certain words and phrases have been underlined for emphasis.

Section 33 of the CPR deals with the "manner of establishing classification". This section has an impact on the classification of skin and eye irritants. Subsection 1 indicates that a supplier shall use: (a) results from testing that he has carried out; (b) evaluation and scientific judgment based on test results. Subsection 2 indicates that he may use information "of which he is aware or ought reasonably to be aware". Subsection 3 deals with a couple of issues: the OECD Test Guidelines that are referred to in Class D, Poisonous and Infectious Material and what to do in the case of classifying skin and eye irritation where a Draize test was used that does not specifically conform to the OECD Test Guidelines.

The Draize test goes back to at least 1944; it has undergone a number of alterations and modifications over time. The OECD Test Guidelines were clearly based on the Draize test but have some significant differences.

Section 33 (3)(b)(v) of the CPR indicates that any other test or method that is carried out according to "generally accepted standards of good scientific practice at the time" can be used to assess, among other things, skin and eye irritants. To summarize,

Richard Morris *continued*

skin and eye irritants could be judged on the basis of an OECD Test Guideline, the use of a Draize test or any other test which was carried out under accepted standards of good scientific practice.

The first criterion under Section 60(a) deals specifically with skin irritation. The test that's alluded to here is the OECD Test Guideline No 404. It deals with two effects: erythema (redness of the skin) and edema. The actual numbers for the grades in the criteria were chosen by the WHMIS criteria working group as reasonable cut-offs to indicate that skin irritation had occurred. Section 60(b)—the criteria for eye irritation—deals with cornea damage, iris damage and conjunctival swelling or redness and refers to OECD Test Guideline No 405. As we will see, the OECD test differs significantly from the test that is recommended in OSHA.

Section 63 deals with untested mixtures. If an ingredient is a skin or eye irritant and is at a concentration of 1% or more, the mixture would be classified as a skin or eye irritant.

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Excerpt from OECD Test Guideline

"Acute Eye Irritation/Corrosion"

* Initial Considerations

Careful consideration needs to be given to all the available information on a substance to minimise the testing of substances under conditions that are likely to produce severe reactions. The following information may be useful in this regard.

i) Physical chemical properties and chemical reactivity. Strongly acidic or alkaline substances which, for example, can be expected to result in a pH in the eye of 2 or less, or 11.5 or greater, need not be tested owing to their probable corrosive properties. Buffer capacity should also be taken into account.

ii) Results from skin irritation studies. Materials which have demonstrated definite corrosive or severe skin irritancy in a dermal study need not be further tested for eye irritancy, it being presumed that such substances will produce similarly severe effects on the eyes.

iii) Results from well-validated alternative studies. Materials which have demonstrated potential corrosive or severe irritancy need not be further tested for eye irritation, it being presumed that such substances will produce similarly severe effects on the eyes in a test using this guideline.

Richard Morris *continued*

The OECD Test Guideline No 405 gives some indication of what to do in looking at acute eye irritation/corrosion. They included corrosion because of the potential difficulty in predicting before conducting the test whether the effect would be irritation or corrosion.

To summarize the points raised by OECD: if you have physical chemical data or data on chemical reactivity that would indicate that the material is likely to react with tissue, then it would make little sense to test it on the eye; if you have results from testing the skin that already indicate that it's a skin irritant, there is no need to test for eye irritancy; if you have an alternative study that would indicate that the material has an effect in eyes, (for example, in an inhalation experiment) this information could be used.

Slide 35 Differences in methodology – eye

DIFFERENCES IN METHODOLOGY
- EYE -

	WHMIS (OECD T.G. 405)	FDA DRAIZE TEST	OSHA FINAL RULE CPSC (Title 16, 1500.42)
No. of rabbits	3 (recommended)	9	6
Local anesthesia	Yes	No	No
Examination times	1, 24, 48, 72 hrs	24, 48, 72 hrs; 4,7 days	24, 48, 72 hrs
Post-observation period	< 21 days	7 days	3 days
Washing of eyes after treatment	after 24 hrs	none, after 2 and 4 secs	none

Criteria: grade for lesions	CPR 6D(b)
	Cornea: 0-4
	Iris: 0-2
	Conjunctiva:
	Redness 0-3
	Chemosis 0-4
		Cornea: Opacity 0-4
		Area 0-4
		Iris: 0-2
		Conjunctiva:
		Redness 0-3
		Chemosis 0-4
		Discharge 0-3
			Positive reaction in
			Test 1: 4 or more animals show effect,
			if 2 or 3 then
			Test 2: 3 or more show effect,
			if 1 or 2 then
			Test 3: any animal shows effect
			NB. positive effects are stated, no grading system

There are a number of test methods for eye irritation that differ significantly from OECD Test Guideline 405. Some of the differences are likely to affect the classification process.

The number of rabbits differs in the various method, but this wouldn't have a major impact on classification. The use of local anesthetics in the case of the OECD Test Guideline probably represents the recent emphasis on avoiding suffering in animals. The post-observation period differs; this would affect the detection of delayed effects or looking at reversibility or irreversibility of the effect. There is also a difference depending on whether the eyes are washed out after the initial treatment; this could have a considerable effect on the amount of exposure. In criteria for grading the lesions, there are some differences in the various tests by which materials may have been tested; if the test data are available, the grading in the older Draize test for discharge could be ignored.

Richard Morris *continued*

The OSHA Final Rule (Title 16, 1500.42) has a very elaborate scheme for testing. A series of tests are done if it's a positive reaction in less than four animals. If any test subject shows a positive effect after the third test, it must be called an eye irritant. The OECD Test Guideline is much simpler, although it doesn't give you any instructions as to what to do if the effect is only seen in a few animals. For OSHA, only positive effects are stated. Pathological findings are indicated only in a subjective way; for example, there's no actual grading system given in the CFR standard.

Slide 36 Differences in metholoigy – skin

DIFFERENCES IN METHODOLOGY - SKIN -			
	WHMIS (OECD T.G. 404)	FDA DRAIZE TEST	OSHA FINAL RULE/CPSC (16 CFR 1500.41)
Skin preparation	intact	intact and abraded	intact
Dressing	semi-occlusive	impervious material	impervious material
Exposure duration	4 hrs	24 hrs	4 hrs
Observation period	< 14 days	---	---
Scoring times (after beginning of exposure)	4.5-5 hr; 28, 52, 76 hrs	24, 72 hrs	24, 72 hrs
Scores and Criteria	CPR 60(a) erythema: 0-4 edema: 0-4 Positive effect erythema: 2 or more edema - 2 or more	combine 24/72 hr scores for intact/abraded skin : 4 Positive effect < 2 mild irritant 2-5 moderate irritant > 6 severe irritants	average 24/72 hr scores Positive effect 5 or more

For skin, there are also some significant differences in the various test protocols that have been used. In terms of skin preparation, using the abraded skin would obviously tend to generate more substances that would cause irritation; the use of an impervious material in case of the OSHA Rule, instead of the semi-occlusive dressing that's suggested in the OECD Test Guidelines could also affect the results. In term of exposure duration the OSHA Final Rule says 4 hours as does the OECD Test Guidelines, whereas in the earlier Draize tests the skin was exposed for 24 hours.

The observation period is not that crucial, but it would have an impact on determining the extent of reversibility of the effect. Scoring times differ between the various methodologies, but the difference is mostly in the OECD Test Guidelines where it looks at earlier changes in time. The scoring criteria vary significantly between the various systems. In WHMIS, the score is 4 or more if you add up the erythema and the edema scores. It's somewhere between 2 and 5 using the Draize test and is considered a moderate irritant. It's 5 or more in the OSHA Rule. This is an area for judgment.

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Ethylenimine

Physiological Response

Acute Toxicity. Ethylenimine is highly to extremely toxic by all routes of exposure to animals; especially if exposures are repeated (Tables 38.1 and 38.2). The effects in experimental animals have been studied by several groups of investigators (8, 13–15). The high toxicity and the unique effect of ethylenimine on the kidney were recognized as early as 1898 by Paul Ehrlich. The free imine is a potent skin irritant and vesicant. Lesions of the skin are slow to heal. Silver and McGrath (14) exposed mice to measured concentrations of ethylenimine in air for 10 min and found the LC_{50} = 2236 ppm. The animals exhibited signs of irritation of the eyes and nose during exposure. Deaths were delayed, occurring from about 24 hr after exposure throughout the 10-day observation period. Carpenter et al. (15) exposed rats and guinea pigs to concentrations of ethylenimine for varying periods of time (see Table 38.2). They also found that deaths were delayed. The animals exhibited extreme respiratory difficulty after exposures to concentrations above 10 ppm and there was evidence of irritation of the eyes and nose at 100 ppm. Repeated 7-hr exposures for several months to 1.65 ppm caused essentially no effects. However, similar exposure to 3.5 ppm caused illness and death in several species (8).

It was determined experimentally that eye and nose irritation in humans becomes evident at about 100 ppm (15).

ETHYLENIMINE

CAS RN: 151564 NIOSH #: KX 5075000
mf: C_2H_5N; mw: 43.08

TOXICITY DATA: 3

	CODEN:
eye-mus 2 ppm/1M	JIHTAB 30,7,48
skn-rbt 10 mg/24H	JIHTAB 30,63,48
eye-rbt 2 mg SEV	AJOPAA 29,1363,46
mmo-omi 600 ppm/2H-C	DBANAD 31,1477,78
mmo-omi 500 mg/L	AMBBBR 6,15,74
dlt-oin-par 20 mmol/L	MUREAV 15,67,72
dni-hmn:hla 500 umol/L	CNREA8 38,4445,78
cyt-hmn:lym 1 umol/L/1H	ARTODN 46,61,80
cyt-rat-ihl 8 ug/L/17W	TPKVAL 13,51,73
dni-mus-ivg 1 pph	JIDEAE 62,378,74
scu-mus TDLo:41760 ug/kg (6-14D preg)	NTIS** PB223-160
scu-rat TDLo:20 mg/kg/67D-I:NEO	BJPCAL 9,306,54
orl-mus TDLo:235 mg/kg/76W-C:CAR	JNCIAM 42,1101,69
scu-rat TD:10 mg/kg/8W-I:ETA	BJPCAL 9,306,54
orl-rat LD50:15 mg/kg	JIHTAB 23,259,41
ihl-rat LCLo:25 ppm/8H	JIHTAB 30,2,48
ipr-rat LD50:3800 ug/kg	BCPCA6 14,915,65
ihl-mus LCLo:1800 mg/m3/10M	NDRC** NDCrc-132,Aug,42
unk-mus LD50:15 mg/kg	BJCAAI 6,160,52
ihl-gpg LCLo:25 ppm/8H	JIHTAB 30,2,48
skn-gpg LD50:14 mg/kg	JIHTAB 30,63,48

Carcinogenic Determination: Animal Positive IARC** 9,37,75.

THR: HIGH irr of skn, eyes, mu mem and via oral, dermal, ipr and inhal routes.

KX5075000 ETHYLENIMINE
UPDT 8611 CAS: 151-56-4 MW: 43.08 MF: C_2H_5N
SYN: AETHYLENIMIN (German) * AMIDOETHYLENE * AZACYCLOPROPANE * AZIRANE * AZIRIDIN (German) * AZIRIDINE * 1H-AZIRINE, DIHYDRO- * DIHYDROAZIRENE * DIHYDRO-1H-AZIRINE * DIMETHYLENIMINE * DIMETHYLENIMINE * EI * EMT-3033 * ETHYLEENIMINE (Dutch) * ETHYLENEIMINE * ETHYLENE IMINE, inhibited (DOT) * ETHYLIMINE * ETILENIMINA (Italian) * RCRA WASTE NUMBER P054 * TL 227 * UN 1185 (IOC)

IRRITATION DATA AND REFERENCES:

eye-mus	2 ppm/1M	JIHTAB 30,7,48
skn-rbt	10 mg/24H open	JIHTAB 30,63,48
eye-rbt	2 mg SEV	AJOPAA 29,1363,46

MUTATION DATA AND REFERENCES:

mmo-sat	1 pph	AGACBM 4,286,74
mmo-sat	10 ug/plate	PNASA6 72,5135,75
dnr-sat	1 pph	AGACBM 4,286,74
mmo-esc	1 pph	AGACBM 4,286,74
dnr-esc	1 pph	AGACBM 4,286,74
mma-bas	19300 nmol/L	JACBBD 25, 3,75
dnr-bas	800 mg/L	EVSIBT 24,19,81

REPRODUCTIVE EFFECTS DATA AND REFERENCES:

1T02	ihl-rat TCLo:800 ug/m3/24H (10 male)	TPKVAL 14,16,75
3T41T42T43	scu-mus TDLo:41760 ug/kg (6-14D preg)	NTIS** PB223-160
2T31T35	scu-mus TDLo:41760 ug/kg (6-14D preg)	NTIS** PB223-160

TUMORIGENIC DATA AND REFERENCES:

2V02V10	scu-rat TDLo:20 mg/kg/67D-I	BJPCAL 9,306,54
2V01L60	orl-mus TDLo:6300 ug/kg/3D-I	VOONAW 27(5),88,81
3V01J60L60	orl-mus TDLo:235 mg/kg/76W-C	JNCIAM 42,1101,69
2V03V10	scu-rat TD :10 mg/kg/8W-I	BJPCAL 9,306,54

TOXICITY DATA AND REFERENCES:

	orl-rat LD50:15 mg/kg	JIHTAB 23,259,41
*	ihl-rat LC50:100 mg/m3/2H	BSGMAT ,,67,82
	ipr-rat LD50:3800 ug/kg	BCPCA6 14,915,65
*	ihl-mus LC50:400 mg/m3/2H	BSGMAT ,,67,82
	unk-mus LD50:15 mg/kg	BJCAAI 6,160,52
*	ihl-rbt LCLo:100 mg/m3/2H	BSGMAT ,,67,82
	ihl-gpg LCLo:25 ppm/8H	JIHTAB 30,2,48
	skn-gpg LD50:14 mg/kg	JIHTAB 30,63,48

REVIEW AND REFERENCES:

★ CARCINOGENIC REVIEW,ANIMAL POSITIVE	IARC** 9,37,75
★ TLV-TWA 500 ppb (skin)	DTLVS* 4,186,80

STANDARDS & REGULATIONS:

★ OSHA-carcinogen	FEREAC 39,3736,74
★ OSHA STANDARD-air:TWA 1 mg/m3 (skin) (SCP-W)	FEREAC 39,2234,0,74
★ DOT-HAZARD-FLAMMABLE LIQUID; LABEL/FLAMMABLE LIQUID AND POISON	CFRG88 49,172.101,82

STATUS:
"NIOSH MANUAL OF ANALYTICAL METHODS" VOL 5 2000
"NIOSH MANUAL OF ANALYTICAL METHODS" TO BE REVISED BY JUNE, 1985
REPORTED IN EPA TSCA INVENTORY, 1983
★ EPA GENETIC TOXICOLOGY PROGRAM, JANUARY 1984
MEETS CRITERIA FOR PROPOSED OSHA MEDICAL RECORDS RULE

Richard Morris *continued*

I'd like to give you some idea of the difficulties of professional judgment. To give you some idea of what sort of data you're likely to see in source materials—the example from Patty is fairly verbal, it references the studies, and it usually gives some sort of conclusion, such as moderate irritation of the skin. Is that good enough? Having raw data, makes it a lot easier, but how many people are going to have access to raw data? If we refer to the excerpt from Sax, he uses terms such as a moderate skin irritant in rabbits and a severe eye irritant in rabbits. There is no literature reference and no indication of grading. How does one interpret this? In RTECS, what you expect to see under irritation data is some indication of the dose, some detail as to whether it was an open or occluded dressing and the actual references. This information is very helpful. There are bound to be some difficulties in dealing with skin and eye irritation because few people have access to the raw data, and they are going to have to use conventional data sources which tend to use words such as "moderate", or "slight".

It, therefore, would be difficult to use the actual WHMIS criteria for skin and eye irritation, such as a grading or scores because of the difficulty of obtaining the relevant data. Why did the working group come up with such criteria if you can't use them? The reasons are not that obscure. We knew that these criteria were going to go into regulations and we had to put them in a form where, assuming that the data did exist, you could use some actual measuring sticks. I suspect future testing would tend to generate data in a way that, if done in Canada, could be more readily used in the classification process.

This illustrates that professional judgment is clearly involved in the classification of skin and eye irritation in the sense that: the raw data are rarely available; sometimes you have to make use of descriptive information; various findings are often from secondary sources; when you are given the information, you may have difficulty finding (as I did in Grant's book Toxicology of the Eye) what sort of grading scheme was applied. It is important not to take numbers of the scores at face value; you have to find out what the basis was for the scoring to see if the data really should be used for classification. The other element important to people in the classification business is how often substances that haven't been tested for toxicity will receive the WHMIS stylized "T" symbol simply because there may be some reason to believe that the material may be an eye irritant. It might be worth discussing the possible impact on WHMIS if a large number of substances are brought into the system only on the basis of eye irritation.

Geoff Granville

With respect to interpretation of skin and eye irritation, the raw data is important to look at; even then you have different protocols for the testing for skin and eye which creates problems in actual interpretation. When it comes to looking at conventional references such as Sax and RTECS, the information is not there which will enable a proper judgment to be made of whether the material is or is not an irritant. That is of major importance when it comes to classification.

Myra Plotnick

I am confused about the corrosion criteria versus the irritation criteria. If you have a chemical substance that is solely corrosive and you have as your warning statement "causes severe burns to the eye and skin," it will most likely also be irritating to the eye and skin. What do you do? Isn't it enough to label it corrosive and have the appropriate warning statement or do you still have to have that "T" symbol?

Richard Morris

This is where professional judgment is really needed because, given that the material that you are dealing with, especially in a mixture, will be at less than 100% concentration, you may well be less concerned about its corrosive properties than about its behaving as an irritant at that concentration. You wouldn't necessarily know that just by looking at the corrosion data but perhaps you could determine it from other data. The OECD Test Guidelines spend some time discussing and clarifying the difference between a corrosive and an irritant. At the same time, this is still a judgment call because it depends on the duration of the exposure itself. Your question is well taken—for example, with workers, does the burning sensation in itself make it an irritant? I think the judgment comes down to whether you're really concerned about it as a toxic substance or whether you want to deal with its chemical reactivity to tissue.

Geoff Granville

If the only means by which a material was captured was based on its corrosive properties, I would just label for corrosion because the "T" symbol is not necessary. If you are dropping down in concentrations and you've got a few other things that are captured, then maybe you'll need a "T" symbol and a "corrosive". For

Geoff Granville *continued*

example, if you've got 5% sodium hydroxide in a material that is otherwise captured for a toxic "T" symbol, then you would probably put both.

Myra Plotnick

If the material that was classified before already met the skull and crossbones symbol, can you stop there? Do you not have the obligation to keep going on, not so much to catch the symbol, but to catch the warning statements?

Geoff Granville

Yes, but the two things are different. One is for the label aspect and the symbols, and the other is entirely for communication of relevant hazards. We do go further for those other reasons.

Steven Lerman

Many times I will read on a supplier's MSDS a statement such as "may cause eye irritation". My sense is that it hasn't been tested. Do you have any guidance on what to do in a case like that? Would you consider it subject to the 1% cut-off, assuming there is no data in RTECS or any of the other reference sources?

Richard Morris

In the face of no actual data, it's perfectly legitimate to say "may cause". It's a judgment call. You have to consider it on a case-by-case basis. I don't think I could say absolutely in every case that I would consider it an irritant. I would have to look at it very carefully.

Steven Lerman

My impression is that concentrations of 1% typically, unless we are dealing with a real corrosive, are not that irritating to the eye for many substances, but may be for a select few.

Richard Morris

I agree. A weak irritant at 100% is not likely to be an irritant that you will be concerned about at 1%. That's one of the things that was built into WHMIS criteria—a certain amount of conservativeness. We all recognize that some substances will probably lose their effect, if you dilute them.

Geoff Granville

If you have a known irritant, a material that meets the irritation criterion and is diluted down to 1%, yes, you're being conservative. But if you have a material which, when it's pure, may be an irritant, but you do not have specific information and you want to dilute that down to 1%, that comes down to judgment. If you don't have the data, there's no drive within the criteria to set you on the way to call that material an irritant. You don't have to. If you think you can find data, do you really think that the material would meet an erythema or an edema score of two? It is purely professional judgment.

Articles

Presenter: Peter Robson
Chairman: Marc Baril

I am going to talk about manufactured articles. When I talk about "articles", I mean manufactured articles within the terms of the regulations. In my own experience of looking at articles in the context of the WHMIS regulations, I discovered that I was initially confused since there was some lack of logic in the way I was trying to classify articles. I have also found that other people were similarly confused. I will go through the logic of the approach I used.

I will cover the definition, in Bill C-70 Section 11, and what is happening in the US with the OSHA Hazard Communication Standard and any guidance or experience from their use of the manufactured article concept. I will have a few examples of manufactured articles and will talk about some classification principles.

The reason that manufactured articles are important is that they are exempted from application of the Federal Hazardous Products Act, Section 12, and exempted completely from the model provincial OSH regulations, Section 2. In reading those two documents, I found that the language in the model OSH regulations makes it quite clear that the exemption only applies if the product in the first case would have been a controlled product.

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EXEMPTION

MANUFACTURED ARTICLES ARE EXEMPTED FROM THE APPLICATION OF THE FEDERAL HAZARDOUS PRODUCTS ACT FOR CONTROLLED PRODUCTS (SECT. 12).

ALSO ARE EXEMPTED COMPLETELY FROM MODEL PROVINCIAL OSH REGULATIONS (SECT. 2).

NOTE:
AN EXEMPTION WILL ONLY APPLY IF THE PRODUCT WAS COVERED BY THE REGULATIONS IN THE FIRST CASE.

The exemption will only apply if the product would have been covered by the regulations in the first case as a controlled product.

This is the definition in Bill C-70. A manufactured article is defined as:

> "any article that is formed to a specific shape or design during manufacture, the intended use of which, when in that form, is dependent in whole or in part on its shape or design, and that, under normal conditions of use, will not release or otherwise cause a person to be exposed to a controlled product."

Peter Robson *continued*

Those three conditions must all be met.

This definition is essentially identical to that which appears on the US OSHA Hazard Communication Standard (29CFR1910.1200). It was deliberately chosen to be the same as the OSHA Standard definition. At this time, we don't have any official WHMIS guidance on how to interpret this manufactured article definition or the exemption that goes along with it. I decided to look at what's happening in the US. There is some guidance in the preamble to the original OSHA Standard in November 1983; there is also guidance in the Field Compliance Notes of OSHA; and in the revised OSHA Standard of August 1987.

These comments are intended to be a technical interpretation about manufactured articles—this is not a legal opinion. The lawyers and the regulators will work on this in due course, and we may obtain conflicting points of view to the one I'm expressing.

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- OSHA STATES:

  THE PURPOSE OF THIS EXEMPTION IS TO ENSURE THAT ITEMS WHICH MAY CONTAIN HAZARDOUS CHEMICALS, BUT IN SUCH A MANNER THAT EMPLOYEES WON'T BE EXPOSED TO THEM, NOT BE INCLUDED IN THE HAZARD COMMUNICATION PROGRAMS.

- THIS PURPOSE IS COMPLETELY CONSISTENT WITH THE INTENT OF THE WHMIS EXEMPTION.

The OSHA Standard says that the purpose of the article exemption is to ensure that items which may contain hazardous chemicals, but in such a manner that employees will not be exposed to them, will not be included in the hazard communication programs under the OSHA Hazard Communication Standard. An OSHA "hazardous chemical" can be considered equivalent to a WHMIS "controlled product".

This exemption of a manufactured article from the scope of the Standard was intended to ensure that items containing hazardous chemicals which are bound within the article so that they are not released, and employees will not be exposed to them, would not

Peter Robson *continued*

be covered by the Standard. This purpose is completely consistent with the intent of the WHMIS regulation. The objective is to exclude products which will present no hazard; it is not to expand the scope of the regulations to cover more products.

There are some important differences to bear in mind when comparing OSHA with WHMIS. The OSHA Hazard Standard has an override with respect to bringing a chemical or product under the scope of the Standard that is not present in WHMIS.

The OSHA Standard requires that mixtures containing hazardous chemical components below the cut-off concentrations, (1% for most chemicals in the US and 0.1% by way of carcinogens only), would be treated as hazardous chemicals if the components can be released in concentrations which would exceed the airborne exposure limit such as the TLV or the OSHA standards, or that release could present a health hazard to employees at any concentration. The use of cut-off concentrations in an untested mixture to cause a product to come within the scope of the OSHA regulations also applies in WHMIS. The OSHA override applies regardless of the concentration of that component in the mixture: if it can be released, then that release would bring the product under the scope of the regulation. This override is not present in WHMIS.

Another thing worth noting is that the WHMIS article definition talks about exposure or release—"under normal conditions of use, will not release or otherwise cause a person to be exposed to a controlled product." That reference to release is the only instance in the WHMIS classification criteria where "exposure" is actively considered. There was a deliberate decision made in the development of the WHMIS classification criteria that these would not be based on risk or hazard which includes the exposure component as well as the toxicity or the hazardous property component. There is no exposure component in the regular classification criteria for WHMIS.

The introduction of this exposure component into the classification will create some problems in applying this article exemption.

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KEY PRINCIPLES FOR CLASSIFICATION OF ARTICLES

- DOES THE MATERIAL/ARTICLE CONTAIN CONTROLLED PRODUCTS AT OR ABOVE THE CUT OFF CONCENTRATION, I.E. IS IT A CONTROLLED PRODUCT?
- DOES IT MEET THE MANUFACTURED ARTICLE CRITERIA REGARDING SHAPE, DESIGN AND END USE?
- IS A CONTROLLED PRODUCT RELEASED UNDER NORMAL CONDITIONS OF USE?
- CONTROLLED PRODUCTS BOUND IN THE ARTICLE ARE NOT CONSIDERED FOR CLASSIFICATION.

These are the key principles for classifying articles. Does the material/article contain a controlled product(s)? Are they above the cut-off concentrations (0.1% or 1.0%)? This leads you to the determination, is this material or product a controlled product? If the answer is no, the WHMIS manufactured article exemption has no significance. You don't apply the manufactured article exemption if the product cannot be classified as a controlled product. That was the most important point.

Peter Robson *continued*

Next, look at the three criteria for the manufactured article; remember, you must meet all three. Does it meet the manufactured article criteria for shape, design and use? Is a controlled product released under normal conditions of use? Another consideration concerns the properties of the controlled products that are released. This manufactured article may contain other controlled products or other hazardous chemicals above the cut-off concentrations, but they are bound in the article; they're not released under normal conditions of use; and they don't count in this determination. The only thing that would trigger you deciding whether this comes into the scope of WHMIS has to do with your determination about release or exposure.

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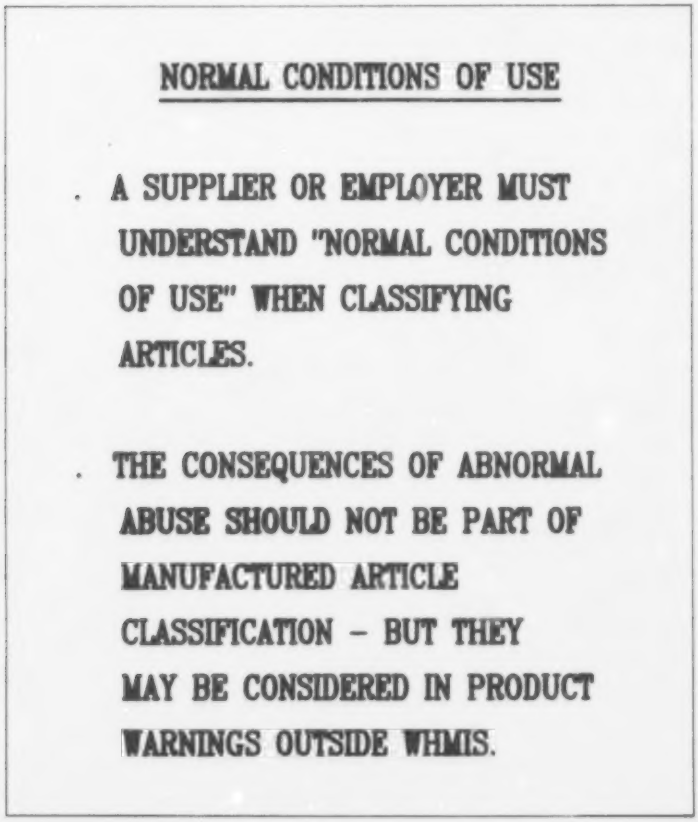
NORMAL CONDITIONS OF USE
. A SUPPLIER OR EMPLOYER MUST UNDERSTAND "NORMAL CONDITIONS OF USE" WHEN CLASSIFYING ARTICLES.
. THE CONSEQUENCES OF ABNORMAL ABUSE SHOULD NOT BE PART OF MANUFACTURED ARTICLE CLASSIFICATION - BUT THEY MAY BE CONSIDERED IN PRODUCT WARNINGS OUTSIDE WHMIS.

Peter Robson *continued*

If you are a supplier manufacturing and selling this product, that creates a burden on you to understand "normal conditions of use". In most cases, that is fairly straightforward; the consequence is that abnormal use shouldn't count here. If someone were to use your manufactured article in a manner for which it was not designed to be used, these criteria shouldn't apply to the determination of release. For example, for most products, abnormal use would include burning the article or cooking it until it was destroyed. There may well be products where part of the intended use is to heat it until it decomposes. but the decomposition products that would come from burning most materials do not count here; it's abnormal use.

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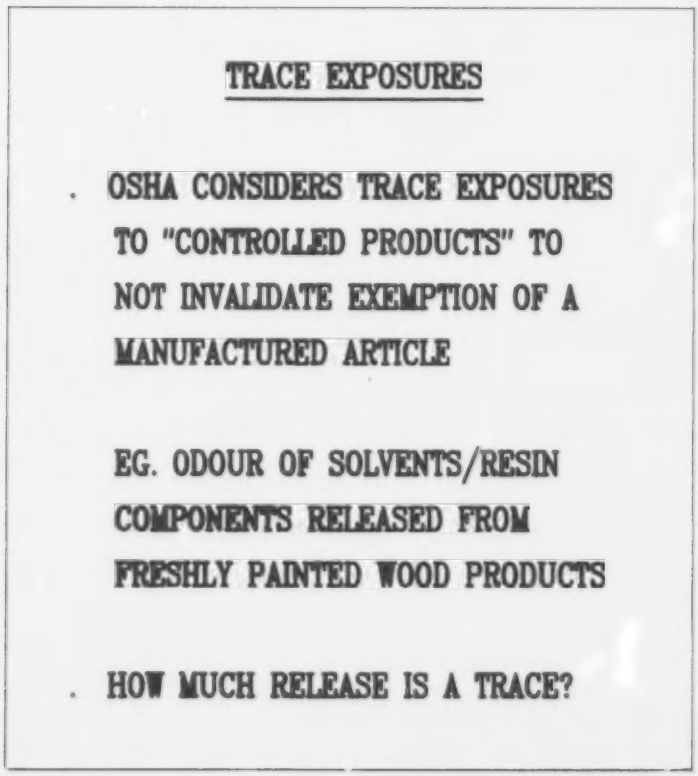
TRACE EXPOSURES
. OSHA CONSIDERS TRACE EXPOSURES TO "CONTROLLED PRODUCTS" TO NOT INVALIDATE EXEMPTION OF A MANUFACTURED ARTICLE
EG. ODOUR OF SOLVENTS/RESIN COMPONENTS RELEASED FROM FRESHLY PAINTED WOOD PRODUCTS
. HOW MUCH RELEASE IS A TRACE?

Peter Robson *continued*

The last item of that definition "is a controlled product released from the article, or is a worker exposed to that release?"

In the August 1987 upgrade of the OSHA Standard there was some discussion about trace exposures or trace releases. My understanding is that OSHA said that trace releases or trace exposures from manufactured articles are not in themselves enough to invalidate the determination to exempt the articles. A tiny release of a hazardous chemical isn't enough to force you to classify that article as an OSHA hazardous chemical; that's a judgment call. For example, if a wooden product has been freshly painted, depending on the paint coating system, a residual odour of solvent would hang around for quite some time—that would represent a release. The solvents are probably flammable liquids or they may contain poisonous vapours. Alone they would be controlled products. You could make a judgment call and say that it doesn't count. Clearly, you could think of a number of applications of that principle.

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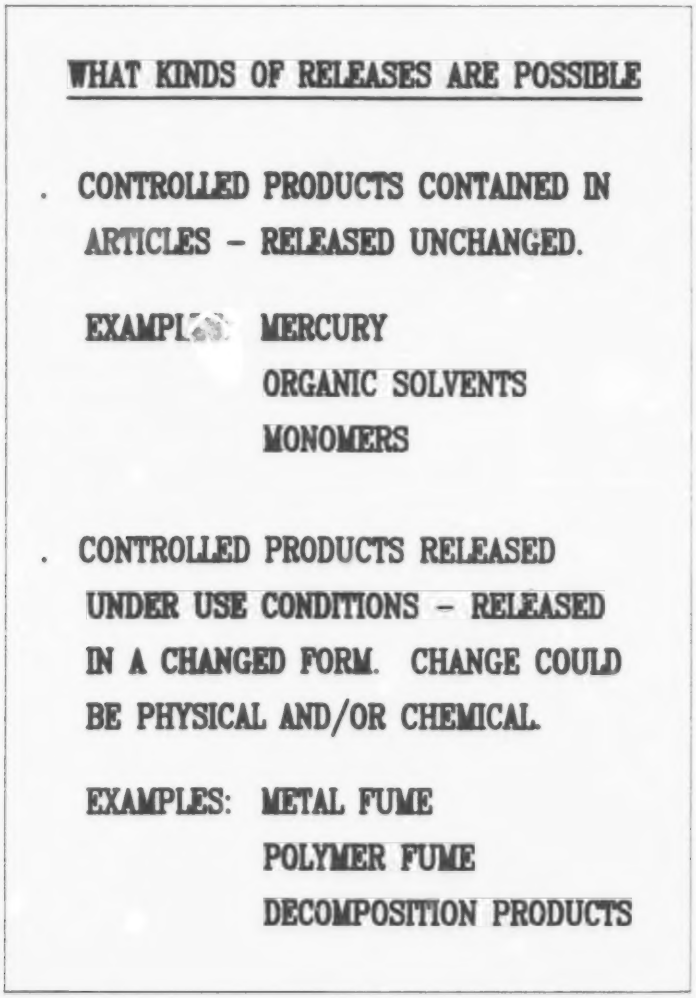
WHAT KINDS OF RELEASES ARE POSSIBLE
. CONTROLLED PRODUCTS CONTAINED IN ARTICLES - RELEASED UNCHANGED.
EXAMPLES: MERCURY
ORGANIC SOLVENTS
MONOMERS
. CONTROLLED PRODUCTS RELEASED UNDER USE CONDITIONS - RELEASED IN A CHANGED FORM. CHANGE COULD BE PHYSICAL AND/OR CHEMICAL.
EXAMPLES: METAL FUME
POLYMER FUME
DECOMPOSITION PRODUCTS

How much release is a trace? Two types of releases are possible. Firstly, where the controlled product, present in the article, is released unchanged. Examples would be mercury which might be contained in mercury switches and released as liquid or vapour; organic solvents present in paint coatings and monomers which are present in an unpolymerized form such as residual isocyanates in polyurethane coatings or polyurethane rubbers.

Peter Robson *continued*

Secondly, you could change the controlled product in the process of it being released under normal use conditions. This change could be a physical form change or a change in the chemistry or both. One example would be metal fume. For instance, if metal fume is released from melting a metal ingot, then you're changing from the massive metal form to fume. This is certainly a change in physical form which goes along with a change in the potential for it to enter the body; typically you oxidize the metal at the same time, so there are two changes going on together. Polymer fume fever can occur if you decompose by overheating a fluorine-containing polymer product such as Teflon. People who overheat Teflon resins and inhale the fume acquire symptoms similar to metal fume fever. Should that be considered a controlled product release? If you overheat polyvinylchloride, you get some release of hydrochloric acid gas. Those are the kinds of things that could happen.

I asked the question earlier: What about these types of exposure? How do we decide whether this exposure is significant or insignificant? Does it change our assessment of whether this is an article? The WHMIS definition of a manufactured article does include the exposure component. It's my belief that in putting together the classification criteria, the manufactured article exemption was intended to be practical. We felt there was a need to address this particular situation, but the intent was not to create a more demanding standard than that which would apply to untested mixtures. In assessing whether something is a manufactured article or whether it can be excluded from the scope of the controlled products regulations, the expectations are that this does not create a more stringent requirement for classification than if you just used the cut-off concentrations for untested mixtures.

We're going to have to use some judgment in deciding where to draw the line in release and exposure. Would the level of exposure or the type of exposure be constant over the life of the product? Would this exposure create a risk to health of workers who are exposed to the controlled product? We are concerned to warn people about the hazards in the products that they buy or manufacture. We'll look at the level of release of the controlled product versus exposure limits and the types of risk. Is this release a potent human carcinogen? Is it a potent respiratory sensitizer, a skin sensitizer or a mild skin irritant? You might worry more about a potent human carcinogen release than you would a mild skin irritant release.

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EXAMPLES

LEAD METAL

LEAD INGOT

- **LEAD IS CONTROLLED PRODUCT**
- **ALWAYS MELTED FOR USE**
- **RELEASES LEAD FUME WHEN MELTED**

THEREFORE IT IS NOT A MANUFACTURED ARTICLE.

LEAD COVERED TABLE

- **INTENDED USE DEPENDS ON SHAPE AND DESIGN**
- **DOES NOT RELEASE LEAD UNDER NORMAL USE CONDITIONS**

THEREFORE IT IS A MANUFACTURED ARTICLE.

An example where we could apply this logic is lead metal. Lead is a controlled product under the WHMIS regulations. The lead ingot is always melted to produce something different—you're going to convert it from one shape to another. In the process of melting, lead fumes are always produced. Therefore, the exemption for an article does not apply because this release is always there; the released lead is a significant toxicity concern.

Another example is a table with some resistant lead coating over it. The three criteria that must be met are: Is it formed to a specific

Peter Robson *continued*

shape or design? Yes. Does the end use depend in whole or in part on that shape or design? Yes. Does it release lead under normal conditions of use? No. Therefore, it is a manufactured article, and the exemption does apply.

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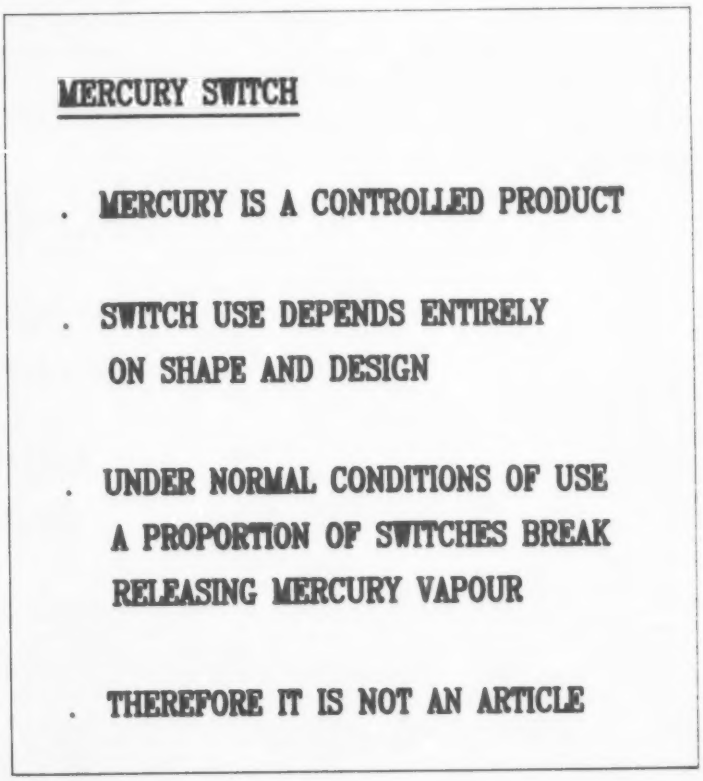
MERCURY SWITCH
. MERCURY IS A CONTROLLED PRODUCT
. SWITCH USE DEPENDS ENTIRELY ON SHAPE AND DESIGN
. UNDER NORMAL CONDITIONS OF USE A PROPORTION OF SWITCHES BREAK RELEASING MERCURY VAPOUR
. THEREFORE IT IS NOT AN ARTICLE

Another example is a mercury switch. OSHA talked about it specifically in the preamble to the 1983 OSHA Standard. Mercury is a controlled product under WHMIS. The switch use depends entirely on the shape and design. Under normal conditions of use, if the switch is in the wall you wouldn't expect it to be broken; however, during shipment it's quite normal for a certain proportion

Peter Robson *continued*

of the switches to break. They would release mercury and you'd have exposure to mercury metal or mercury vapour. Based on this release, OSHA has determined that the mercury switch is not an article, and is therefore not exempted from the scope of the regulations; it would have to be labelled and a warning issued. If an unbreakable switch were invented, no release would occur under normal conditions of use. Clearly the knowledge of the supplier or the user is very critical in making the determination about release under normal conditions of use.

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POLYESTER/STYRENE RESIN PRODUCTS

CAFETERIA TRAY CONTAINING GLASS FIBRE/ POLYESTER/STYRENE THERMOSET RESIN.

- END USE DEPENDS ENTIRELY ON SHAPE AND DESIGN
- MAY CONTAIN RESIDUAL STYRENE MONOMER - A CONTROLLED PRODUCT ≥ 1.0%
- ODOUR OF STYRENE APPARENT WHEN NEW; FADES WITH TIME
- THEREFORE STYRENE IS RELEASED UNDER NORMAL CONDITIONS OF USE

Peter Robson *continued*

An example of a polyester/styrene resin product is a cafeteria tray. DuPont Canada has moved into new offices in Mississauga. While walking to the newly opened cafeteria I could smell styrene; I could not think where it was coming from until I picked up the tray, and then I knew—it was the tray that smelled of styrene. This tray is fiberglass reinforced polyester/styrene resin tray—the kind of thing we see very frequently in cafeterias. It was brand new. That I could smell styrene means that styrene was being released.

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STYRENE

. **ACGIH TLV =**
50 ppm – 8 hour TWA
100 ppm STEL

. **ODOUR THRESHOLD =**
0.3 ppm

. **LOWER FLAMMABLE LIMIT =**
1.1% VOLUME

What do we do about classifying such a product? The same principles apply to a styrene/polyester corrosion-resistant tank for holding workplace chemicals. The end use depends entirely on the shape and design. I will assume for the purpose of this exercise that this does contain residual styrene monomer and the level is above the 1% cut-off for styrene. The odour of styrene is apparent when the article is new and it fades rapidly with time; after a few days, the smell was essentially gone. There is no constant exposure with use of this product. Is a health hazard involved? I believe not. The ACGIH TLV for styrene is 50 ppm TWA and 100 ppm

Peter Robson *continued*

STEL 15 minute short term exposure. The odour threshold is extremely low; it's 1/3 of a ppm. The lower flammable limit, which is the other possible concern, is 1.1% by volume. I believe that the extremely low threshold odour level and the observation that the odour quickly faded with time meant that this exposure was not significant and need not be taken into account in trying to decide whether this was an article or not. Therefore, the article exemption would apply. The principle involved here is that trace releases or exposures to controlled products from articles should not invalidate the manufactured article exemption.

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WELDING ROD

- **CONTAINS > 1% OF CONTROLLED PRODUCTS**
- **INTENDED USE ALWAYS PRODUCES METAL WELDING FUME**
- **FUME CONTAINS CONTROLLED PRODUCTS**
- **THEREFORE IT IS NOT A MANUFACTURED ARTICLE**

A welding rod contains greater than 1% of a variety of metals; some of those metals are controlled products so we apply the

Peter Robson *continued*

following logic. Would the article itself meet the criteria for classification as a controlled product based on cut-off concentrations of the ingredients? The answer is yes. The intended use most definitely depends on its shape and design. Whenever welding rods are used, a metal welding fume is produced. This fume does contain controlled products, therefore, we do not meet all the criteria for the exemption and the welding rod would become a controlled product.

My objective in making this presentation was to go through a process of logic, sparked by my own puzzlement, in trying to unravel this process.

When applying the article exemption in WHMIS, first, evaluate the composition of the product and decide whether it would be a controlled product based on its composition; if it wouldn't, that product is not covered by the WHMIS regulations. If it would meet the composition requirements to be a controlled product then you look at the three criteria for a manufactured article, and the key is usually release of the controlled product. What is the nature of the release? Is it chemically the same as the product components? What is the time frame of the release? Is it a constant release under conditions of use? Is it a temporary release? What's the level of release, for example, is it a trace or significant level? What are the health consequences of the release?

Ugis Bickis
Occupational Health Centre, Queen's University

I have a question for Peter that deals with the interpretation of the words exposure and release. You're suggesting that only airborne release is to be considered. My question deals with your example of the lead-covered table. If someone is working at the table and is in hand contact with the lead surface, lead oxide could in fact be released from the surface to the fingers. The principle of hazard training would include informing the individual that lead oxide film could be transferred to the mouth through oral route and it could be hazardous. Does the definition for release or exposure in this context specifically identify airborne?

Peter Robson

The examples that I used were related to airborne releases. But clearly, any exposure route has to count. I can think of a number of manufactured articles made from polymers such as synthetic

Peter Robson *continued*

rubbers. These products are typically compounded with additives and some of the additives migrate to the surface. For example, let's suppose that the composition of the rubber on the cafeteria tray met that criterion, there could be enough styrene left in the tray for a film of styrene on the surface—clearly there's an opportunity for exposure.

In the case of the lead table, unless you deliberately grind lead, rub it or convert it to a form where it can be transferred, I would regard that as a very low risk and would not consider such a possible release to not invalidate the article classification. But that's a judgment call.

Gerald Gough
Dow Chemical Canada Inc

I've had the same uncertainties. It seems that you have already decided in advance, for example, that a welding rod is a controlled product if it's not an article or that a lead ingot is a controlled product, unless you classify it as a manufactured article.

I take exception at the first step where you say lead is a controlled product. Is it a controlled product? You have to go through that initial exercise of classifying lead metal, determine if it's a controlled product and then look at the article and determine if it's an exemption under the manufactured article exemption in the regulations. I get the impression that the process is backwards.

Peter Robson

I agree. All that I've done is to short-circuit the process. I selected materials which I was quite confident were controlled products; I did not go through the classification. Most would agree that lead, mercury and styrene meet the criteria for a controlled product. I didn't want to go through the classification. The issue I wanted to address was how to get from that to looking at the article exemption. You must classify the substances present in the manufactured article first.

Marvin Havery
Canada Colours & Chemicals Ltd

I have a question that affects us very much and it concerns the 6,000 different compounds that we're involved with. These are colour concentrates which are resins such as high density

Marvin Havery *continued*

polyethylene, polypropylene and PVC that contain various types of pigments and stabilizers. They are in the form of extruded pellets. For example, the polyethylene pellet could contain 50% lead chromate which is carcinogenic and is on the Ingredient Disclosure List at 0.1%. Are these controlled products?

Peter Robson

The three criteria for deciding whether something is a manufactured article are used. First, it's formed to a specific shape or design. Secondly, the intended end use depends in whole or in part on that shape or design. If we apply these criteria to resin pellets, the determination is they are not articles because the pellets are not used in this form. In my assessment, the manufactured article would be the product that you make. For example, it could be a child's toy or any other molded or extruded article which is formed to a specific shape or design.

You could feed your molding machine with resin in a variety of sizes and shapes, it would still function; that's not critical to the end use of the product. I believe that in the United States, OSHA has taken the view that polymeric resins supplied in pellet or powder form are not articles. I would look at how I would classify this as a controlled product. I have the polyethylene resin; I have, say 10% lead chromate; I may have some stabilizers which are well below 1% and don't count. But, if the chromate is over 0.1%, it's considered a controlled product because lead chromate itself is a controlled product and the untested mixture rule would apply.

Marvin Havery

How would you test a product that comes in a pellet form? For example, in a toxicity test, how would you feed animals this product?

Peter Robson

I went through a process for evaluating untested mixtures about a year ago; when the concept was how do you test out of WHMIS? The situation you describe is very common in industry; we're all going to be facing it. The "logic" I used was to search for the available data on the ingredients or the mixture and then to classify each of the ingredients based on the data. For example, I look at toxicity for polyethylene and lead chromate, and the only relevant data I have is for one ingredient, lead chromate pigment. I find

Peter Robson *continued*

it's on the IARC carcinogen list, and the NTP carcinogen list. If I want to test my way out, there's no way to do it. The WHMIS classification rules do not appear to allow this for carcinogens.

Suppose the pigment only showed toxicity with respect to skin irritation. Which test or tests have to be completed to test it out of WHMIS? The approach I would take is to ask why am I testing this untested mixture? I'm testing it because one ingredient showed up as being a skin irritant—that's for the pure substance. If I want to test the untested mixture, I need only test it for that parameter for which I found data, which is skin irritation. So that's what I test it for. That's an economic decision. You make a judgment call on the impact of the WHMIS classification versus the cost of testing and the likelihood of achieving test results which will override classification by cut-off concentration of ingredients.

Marc Baril

You mentioned constant exposure versus life of the product. How long is that exposure period? Is it an article which will emit a substance for 6 months or a year, even if the life of the product is 20 years.

Peter Robson

That's a good point. I think the exposure period is probably more important than the life of the product. Some products are long-lived and others are short-lived such as the lead ingot; as soon as you dump it in the vat and melt it, it's gone. As long as you keep it in the melt pool you have the potential for an exposure to fume. I think you're correct; the primary emphasis should be on the period of exposure in deciding whether you're going to regard this as significant exposure.

Classification of Material 2

Presenter: Marc Baril
Chairman: David Gaylor

The second product is a completely different product from the one classified this morning. It involves more of a legal judgment than a scientific judgment.

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MATERIAL # 2

Review of element TiO_2

- Titanium dioxide:	1)	not listed		
	2)	class A:	compressed gas	N/A
	3)	class B:	flammable and combustible material	N/A
	4)	class C:	oxidizing material	N/A
	5)	class D:	poisonous and toxic material d_1	N/A
			d_2	N/A
			TCLO 250mg/m^3/6H/2Y-I inhalation not low enough: rat* d_3	N/A
	6)	class E:	corrosive material	N/A
	7)	class F:	dangerously reactive material	N/A

* Toxicology and Applied pharmacology 79, 179, 85.

That product is a mixture of 98.5% titanium dioxide, 1.5% crystalline silica and .2% chromate.

The first element of the material is titanium dioxide. It is obviously not a compressed gas, not a flammable material, not an oxidizing material, but it has a TCLO of 250 mg/m^3/6H/2Y-I, inhalation, not low enough in a rat. It is not a corrosive material and it's not a Class F—Dangerously Reactive Material.

Slide 50 **Material # 2**

Review of element SIO_2

1.5% crystalline silica

1) Disclosure list .
Crystalline silica is listed either as cristobalite, quartz, tridymite or tripoli. Therefore, the manufacturer should identify which one is included in his mixture and list it.

If it is a mixture of silica*, all forms present in more than 1.0% should be listed.

Note: pure SIO_2 occurs in only 2 forms: quartz and cristobalite*.

2)	Class A:	compressed gas	N/A
3)	Class B:	flammable and combustible material	N/A
4)	Class C:	oxidizing material	N/A
5)	Class D:	poisonous and toxic material	N/A

All forms of crystalline silicas have been tested in rats either intratracheally and/or intrapleurally; therefore, it is not in accordance to OECD #452 and 413.
On top of that, the LDLO are greater than 100 mg/m^3 and not in a toxic group according to WHMIS criteria.

6)	Class E:	corrosive material	N/A
7)	Class F:	dangerously reactive material	N/A

*Advanced Inorganic Chemistry (Cotton G. Wilkinson, p. 386)

Marc Baril *continued*

The second component is completely different—1.5% crystalline silica.

It is important to note that $SI0_2$ occurs in only two forms: quartz and cristobalite. It's not a Class A product—Compressed Gas; it's not a Class B—Flammable and Combustible Material; it's not a Class C—Oxidizing Material. All forms of crystalline silicas have been tested in rats intratracheally and/or intrapleurally; and is very far from OECD Guidelines No 452 and 413. The LDLO are greater than 100 mg/m^3 and are not in a toxic group according to the WHMIS criteria.

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Conclusion:

Considering the WHMIS criteria and the data gathered in the litterature, none of the crystalline silica would need to be listed on account of their toxicity. Mainly because the inhalation studies have been performed intratracheally or intrapleurally and therefore not according to OECD 452 and 413. However, since all forms of crystalline silica are listed in the disclosure list, it seems that the manufacturer will have to list any forms present in CONC. > 1%. If no forms are present in CONC. > 1%, the silica should not be disclosed. But the possibility for pneumoconiosis should appear in the toxicological properties.

Considering the WHMIS criteria and the data gathered in the literature, none of the crystalline silicas would need to be listed on account of their toxicity. Mainly because the inhalation studies have been performed intratracheally or intrapleurally and not according to OECD Guidelines No 452 and 413.

Since all forms of crystalline silica are listed in the Ingredient Disclosure List, it seems that the manufacturer will have to list any forms present in concentrations > 1.0%. If no forms are present in concentrations > 1.0%, the silica should not be disclosed, but the possibility for pneumoconiosis should appear in the toxicological properties of the MSDS.

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Material # 2

Review of element CRO_4^{-2}

Zinc chromate	Conc. $\leq$ .1%	not listed
Lead chromate	Conc. $\leq$ .1%	not listed

However, CHROMIUM (VI)
(certain insoluble salt)

Should be disclosed as an "ingredient" on account of their cancer causing potential ACGIH: A1. Some insoluble chromium (VI) are covered by ACGIH and both $ZNCRO_4$ and $PBCRO_4$ are insoluble.

Even if the notion of CRO_4^{-2} or CR(VI) being an ingredient can be debated, the fact remains that in the disclosure list, families of compounds are considered "ingredients".

The situation would have been different if we had had benzene $>$.1% and arsenic $>$ .1%. Then, none of them would need to be disclosed. But the question of additivity of cancer causing potential should be considered in the elaboration of the Toxicological properties section. There, one may want to EXAMINE the mechanis of tumor induction and/or promotion of each chemical to assess the possible additivity in the cancer causing effect.

In the third element, each of the two salts, zinc chromate and lead chromate, are at the concentrations of .05%, well below the 0.1% cut-off point. That means that they will not have to be listed, and they will disappear. The problem is that chromium (VI) (certain insoluble salt) appears on the list of carcinogenic substance. In our view, chromium (VI) should be disclosed as an "ingredient" on account of its cancer-causing potential, ACGIH: A1. Some insoluble chromium (VI) are covered by ACGIH, $ZNCRO_4$ and $PBCRO_4$ insoluble. Even if the notion of CRO_4^2 or CR (VI) being

Marc Baril *continued*

an ingredient can be debated, the fact remains that in the disclosure list, families of compounds are considered "ingredients".

The situation would have been different if we had had benzene < 0.1% and arsenic < 0.1%, then, none of them would need to be disclosed. But the question of additivity of potential cancer should be considered in the elaboration of the Toxicological properties section. In that specific case, you will have to ask yourself: Is the same organ touched? Is the same mechanism involved? There is nothing in the legislation concerning additivities of cancer agents. One may want to examine the mechanism of tumor induction and/or promotion of each chemical to assess the possible additivity in the cancer-causing effect.

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OVERALL MATERIAL 2

A	compressed gas	N/A
B	flammable and combustible material	N/A
C	oxidizing material	N/A (1)
D	material causing other toxic effets	D2A (2)
E	corrosive material	N/A
F	dangerously reactive material	N/A

1) The question of how much of an oxidizing agent should be present in a mixture for it be considered included in Class C should be examined.

2) There is a contradiction between the ingredient disclosure list which states that chromium (VI) compounds should be declared if present at concentration ≥ 1% and the fact that according to the cancer causing effect criteria, it is≥.1% for certain insoluble chromium (VI) salts.

Overall, material 2 is not a compressed gas; it is not a flammable and combustible material; it is not an oxidizing material. The CSST staff who classified Material 2 were not involved in WHMIS. Some staff have been involved with the criteria all along since 1981.

Marc Baril *continued*

but we tried not to use these people in classifying Material 2. We wanted no bias of any kind, so we used "fresh" chemists and biochemists.

One of the questions we asked was how much of an oxidizing agent should be present in a mixture for the need of considering it for inclusion in Class C should be examined. There is a small line missing in the recommendation over there. It would be interesting to debate it. We already mentioned the contradiction between the Ingredient Disclosure List which states that chromium (VI) compounds should be declared if present at concentration > 1.0% and the fact that according to the cancer causing effect criteria, it is > 0.1% for certain insoluble chromium (VI) salts.

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ELEMENTS TO BE DECLARED ON THE MSDS

1. Hazardous ingredients

		Comments
Chromium (VI)	Certain water insoluble .1%	- Based on ACGIH Chromium (VI) some water insoluble compound
No. CAS	mixture	
LD50	not applicable	
LC50	not applicable	

Form? of crystalline silicas, ? %

CAS: see disclosure list
LD50: not available
LC50: not available

- Crystalline silica should be disclosed only for the forms present in excess of 1.% with the corresponding CAS. No LD50 or LC50 available in RTECS.

2. Preparation information
-
3. Product information
-
4. Physical data
-
5. Fire or explosion
-
6. Reactivity data
-
7. Toxicological properties
-

Route of entry: lung, eye contact, skin contact

- Acute exposure: N/A — No real acute effects
- Chronic exposure:

  Possibility of pneumoconiosis and silicosis — TiO_2 : benign pneumoconiosis; Silicosis if any (silica) > 1%

- Exposure limits:

TLV	Regulation (Que.)
Chromium VI 0.05mg/m^3 (Certain water insoluble)	Chromate .05mg/m^3 (Certain insoluble salt)

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continued

- crystalline silica respirable dust		Consult Quebec Regulation	TLV listed depends of the nature of the silica
	-cristobalite 0.05mg/m^3*		
	-quartz 0.1mg/m^3 *		
	-silica (fused) 0.1mg/m^3*		
	-trydimite 0.05mg/m^3*		
	-tripoli 0.1mg/m^3 contains respirable quartz		
* respirable dust			
Titanium dioxide 10mg/m^3		10mg/m^3	
-Cancerogenicity:	⊕		Chromium (VI) certain insoluble salt.

Preventive measures

- ventilate to keep exposure below the TLV and regulation
- avoid all contact (cancer causing agent)

Chromates

Chromium (VI) (Some water insoluble compound)	1)	Disclosure liste Cr. (VI)<1% CR (VI) (some water insoluble) <.10% disclosed	N/A
	2)	Class A: compressed gas	N/A
	3)	Class B: flammable and combustible material	N/A
	4)	Class C: oxidizing material	N/A
	5)	Class D: material causing other toxic effect	D2A
	6)	Class E: corrosive material	N/A
	7)	Class F: dangerously reactive material	N/A

Marc Baril *continued*

We tried to deduce the elements that must be declared on the MSDS. In terms of hazardous ingredients, chromium (VI) will appear as being a certain water insoluble 0.1% based on ACGIH. Forms of crystalline silica should be disclosed only for the forms present in excess of 1.0% with the corresponding CAS; no LD_{50} or LC_{50} is available in RTECS. The rest is the MSDS itself: preparation information, product information, physical data, fire or explosion data and reactivity data.

Under toxicological properties: lungs (especially for silica), eye contact and skin contact are possible routes of entry. It must be mentioned that there's also a possibility of pneumoconiosis and silicosis.

Under exposure limits: another problem we are facing is that the ten provinces in Canada plus the federal government result in 11 different TLVs on a single product. If you use the TLVs from the United States, it will be different from the TLVs being used in each province of Canada.

Under preventive measures: ventilate to keep exposure below the TLV and regulation and, avoid all contact with cancer causing agent. There are a lot of questions concerning the way we deal with chromium. We could consider it as two different products. The Ingredient Disclosure List didn't give us much choice; we had to disclose chromium as a total ingredient.

Lillian Vine

We are going to repeat the procedure of this morning; the panel members will discuss what processes they would have used for this material, and what results they would have obtained. Your comments and questions are welcome.

Geoff Granville

My first comment is on crystalline silica. In the absence of specific information on the breakdown from that 1.5% crystalline silica, I would include the potential for pneumoconiosis and silicosis. I feel that that would be the proper thing to do in that circumstance; that's my judgment.

The second comment is on chromates. You didn't mention irritations and sensitizations. One of the things I would worry about is respiratory sensitization from chromates; in that format of 0.1%

Geoff Granville *continued*

total chromates in a solid material, I wonder what the respiratory problem could be like. I'd like to know what your group thought.

Marc Baril

For crystalline silica, it depends on which compound is used. There are four types of crystalline silica, but only two are considered as crystalline silica directly. On the MSDS under chronic exposure, pneumoconiosis and silicosis will appear depending on which compound is used. We opened the subject, but we didn't respond because it depends on whether the manufacturer identifies which one is included in his mixture and/or lists it.

The problem with chromium (VI) is its different classes. Looking at the literature, chromium (VI) was usually seen as an irritant, but it is always mentioned as a class of products. You can never be sure what kind of salt has been used. It's rare to have enough raw data to find out the kind of salt that has been tested. We could try to find all the information related to zinc chromate and lead chromate which would help solve the problem. If any of them were an irritant, we could add to it. We decided to use the classification as a family.

Peter Robson

There was one particular issue that I was interested in; it's the adding of low level ingredients. The first two chromates were deliberately chosen because each of them was below 0.1%, but together they came to 0.1% which is the cut-off. You address it as the additive effect as opposed to being quite different effects. From your perspective, how would you approach a situation where you might have two strong eye irritants present in an untested mixture and each of them is below 1.0% in the mixture, but the sum of these together exceeds 1.0%; it's the identical toxic effect that we're looking at.

Marc Baril

It's a matter of judgment. Legally, from the point of view of urgency, my job will be to look at some MSDSs and say "As a manufacturer, you didn't do your job very well, so we'll sue you". From the point of view of people like us who will have to look at MSDSs, we'll start to look at ingredients first just to be sure if they will or will not appear. At -0.1%, there will be no problem. From the toxicologist's point of view, if you add a very small

Marc Baril *continued*

amount of product in terms of concentration, you add activities such as irritation or toxicity, I think you have to indicate it on the MSDS.

This is purely on the judgment point of view, not specifically on the law because the law is focused on constituent; normally at less than 0.1%, the constant will disappear and everything with it will disappear. Any kind of activities of that specific component will have to appear on the MSDS. It's your ability as a toxicologist, chemist or biochemist or an engineer to decide if the information will appear on the MSDS.

Robert Whiting

I must admit I didn't spend a week on this one, but I have a few points. We've looked at silica and our tendency is to classify it as a very toxic material under the "T" symbol because of the ample human evidence for which there is dose response information. The criteria for very toxic material under chronic toxic effects say, "a serious toxic effect—10 mg/m^3 exposure"; there's certainly lots of evidence that it's as low as 1 mg/m^3 for granite workers. On that basis, in the absence of animal data, we thought we would classify it as a very toxic material; that is not something that is required by the criteria, but that was our judgment.

I agree with what seems to be the conclusion of most of the speakers that because we have two insoluble chromates both of which are specifically listed in a number of sources as being carcinogens, we ought to take them as being toxicologically similar and regard the mixture also as being very toxic. I think it would be quite different if one of them wasn't a soluble chromate; the decision would have to fall on the other side in that case.

I am rather intrigued by the question of whether the product might be an oxidizing agent. I suspect that this particular product would not. I was looking at the actual criteria which say, "an oxidizing material is one which causes or contributes to the combustion of another material by yielding oxygen or oxidizing substance or is an organic peroxide". In this case, chromates are not organic peroxides, and the chromates themselves are not very strong oxidizing agents, although the pure material would be, in a fire. I suspect that the level of the chemicals in this product wouldn't be oxidizing agents; it's something that needs to be considered. If it rose to 10-20%, it might be worth testing.

Marc Baril

During the review, we pinpointed the problems; we decided to add it to the list even if there's no real relation to the product itself. The problem with silica is that, on the list, there are four of them: cristobalite, quartz, tridymite or tripoli, but there are really only two which are considered crystalline silica: quartz and cristobalite.

Robert Whiting

In terms of toxicology, if most evidence exists for quartz and if the only other likely candidate is cristobalite (which would actually be crystalline silica), and according to the documentation of TLVs, cristobalite is more fibrogenic than quartz, I think we would have to assume that no matter what kind of crystalline silica was there, it would have to be regarded as probably very toxic within that category of having a silicotic effect at a very low dose.

Richard Morris

The interesting thing that comes out of this is the whole question of the additive properties of more than one substance. I know that during the process, we wondered what would happen if somebody developed a solvent mixture where all the toxic solvents used were deliberately below 1% to avoid having to disclose them. That's hypothetical. I think the judgment would tend to be along the line of how serious was the toxic effect that you were trying to avoid disclosing.

The other point would be the target organ. Marc's point about benzene and arsenic in the same mixture was interesting; those are not likely, based on our perception of their carcinogenic properties, to be additives and, therefore, it would seem improper to add them. Whereas the two insoluble chromates theoretically would be additives if they were behaving as insoluble chromates.

As far as crystalline silica, I think that's a very difficult judgment call. Looking at it from the point of view of a manufactured article in the sense of what the end use is, if this thing is really designed to be on a product and is somehow formed and situated such that it wouldn't normally release the silicon, then you wouldn't expect it as a free silica dust. But if you had to spray it onto something and it was, therefore, in a respirable mode, then I think you would definitely have to consider it as part of the classification.

David Gaylor

I have a couple of points to add to sum up what everyone has said. Crystalline silica could easily fall under the chronic toxicity class, since there's a lot of human data attributed to silica. There are no animal studies, but if you're considering the known human effects of silica, you could easily put it under the chronic toxicity category—Division 2 of Class D rating.

The other point is when you're considering the additivity, you should consider whether it's the additivity of the physical hazard effects, oxidizing effects or any of the toxicological effects including corrosivity, irritancy or carcinogenicity, if it's the same target organ and if it's the same mechanism. If the toxic effect has the same mechanism on the same target organ then that should be a consideration by adding the concentrations.

The most important point is what Richard mentioned—whether in normal use the product could release those particular ingredients that could be considered additive. If I were a manufacturer of this product, I would consider how it would be normally used and would the chromates actually cause exposure during its normal use; considering all those things, I would have it classified.

Marc Baril

I agree with you. With additivities we'll have to mention target organ and metabolism; we'll also have to enter kinetics in the process. I think we'll have to agree with or at least use what Gerring and company's people from Dow Chemical in Michigan developed a couple of years back based on methylene chloride. They produced very interesting stuff related to target organ and pharmacal kinetics. For additivity, I think we'll have to regard everything together to be able to pronounce ourselves.

In terms of product release, we touched on that article in a way. It's a debate as to whether it is an article or not.

David Gaylor

I don't know if we have a consensus of opinion on the panel of how this would be classified. First of all, would everybody classify this under chronic toxic effects because of the silica? Yes. And would we add the chromates? Yes.

Guy Ethier
Esso Petroleum Canada

I thought it was very interesting to see the two examples that Marc and Bob classified. Unfortunately, it's not always that easy because we end up dealing with up to thousands of different products and different mixtures. There's an interesting concept in the new CPR that talks about naturally-occurring material. I'd like to get some thoughts on what is a naturally-occurring material especially in untested mixtures. And what if it contains some compounds that could be identified as being toxic, such as benzene?

Marc Baril

It's more an environmental problem than a health and safety problem. You're probably speaking about complex mixtures such as gasoline. It's a very good question. I really don't know how WHMIS will cover it right now. The way WHMIS is built, petroleum products, with a CAS number, will be considered as one substance and not even a mixture. The way I understand it, it will be considered as a simple ingredient, but you need a CAS number with it.

Guy Ethier

What if that simple ingredient has not been tested?

Geoff Granville

I think it's actually quite straightforward, but we haven't gone through the exercise yet. If you have a naturally-occurring complex mixture, for example, a mixture of hydrocarbons; you happen to know it contains some materials which in themselves would be controlled, you assume the mixture is a pure material at first because you don't have to break it out. Do you have any data on that material with the CAS number as Marc just mentioned? If the answer is yes, then you give that information. If the answer is no, you use partly your judgment and partly the intent of the regulations to say what is in that mixture; if you happen to know there's more than 0.1% benzene, that will drive the system. If there's more than 1% toluene, xylene, n-hexane or another molecule, they would also drive the system. You start off by seeing if there's any data out there which relates to the product with the CAS number that is appropriate. I think it's easy, but I think you and I and a few others are going to go through the process for the next few weeks to find out if we're right or not.

Jacques Cerf

I have a comment regarding the classification of the second product. I think that in most cases in industry, when formulation would contain a product below 0.1%, as a rule, people will tend not to classify the product. Each company has a resident toxicologist, and I understand a good one, to use scientific judgment. What do you have to say about getting involved in classifying products with ingredients less than 0.1%?

Marc Baril

In that specific case, we were lucky because on the back list of the WHMIS, chromium was present.

Jacques Cerf

But the list is not supposed to be used to classify products. It's to be used after you have your classification in place.

Marc Baril

The list also contains classes of products. Otherwise these two chromates would have disappeared. The problem with the class is we could put together some very small concentration component. Specifically because it was chromium we were able to do it, but otherwise they are two different assays; for example, one sulfate and one chromium—chromate will have no effect—they will both disappear.

Peter Robson

The feeling I have about the intent of the regulations was that the 0.1% cut-off is a definite cut-off. If the component is present at less than 0.1%, then it doesn't need to be taken into account for the purpose of classification. I think that is quite clear. The purpose of the exercise of this synthetic mixture that was put together was exactly to bring that issue out.

The feeling I have, Marc, about the point that you made, is that it just so happened that if you wanted to consider these two compounds as chromates, then you would indeed have 0.1% of insoluble chromates. The fact that they had two different metals attached to the chromate is another issue. I think there are two ways of looking at that.

If you decided to be quite rigorous in your application of the regulations and say these are two different substances—each of

Peter Robson *continued*

them less than 0.1%, I don't think you could be faulted for doing that. I would think that this approach of adding them, for the reasons that we've talked about and because they have similar effects such as targets organs, would be going a little beyond WHMIS.

John Harrison
LePage's

I want to take Marc's mixture and just change it a little bit. If you had 75% titanium dioxide, 5% crystalline silica and 20% water, then you would have a paste and the silica is no longer airborne. How do I classify that then? Is the silica no longer a hazard even though it's still above 1%?

Richard Morris

The problem I see is that the water will come off and it will dry. A water-based paint doesn't come off easily when it dries; it doesn't easily go back into the solution because it has a polymer in it.

John Harrison

But it's got 5% silica and therefore, it's above the 1% limit. Can I use my professional judgment and say that's not going to be hazardous?

Marc Baril

No. It has to be present.

Richard Morris

The other thing in this judgment process is that you have to look at the consequences if you don't mention it. To try to stretch this thing out to see when the regulators are going to kick in? I don't know whether it would be worth that exercise. The other thing is, what happens if I do mention it? Is someone going to say, "I can't buy your product—you've got this "T" on it—Joe's product doesn't have a "T" on it—I think I'll use the safe product". These are the consequences of labelling. This is the kind of judgment that falls outside simple scientific judgment and goes into the areas of economics and marketing; I don't have to deal with that—others do. I don't know if it comes into play at all; I'm just suggesting that it might.

John Harrison

Actually, it does come into play. This is a big problem.

Geoff Granville

It's not an article until it's on the wall. It's more than 1% silica—you'll have no judgment in this case. That material is a controlled product. You can't use logic. If you deliberately fall outside the requirements of WHMIS, that's where the politics become involved. The front end is given—you've got a product. The fact that there's no exposure is completely immaterial.

Neil Murray

Marc, I need clarification on something that you said. In your discussion on silica, you referred to the list. I assume you mean the Ingredient Disclosure List. It's my understanding that the Ingredient Disclosure List was for that purpose only—ingredient disclosure. And the fact that this material contains 1.5% of crystalline silica, you'd only addressed the fact that it's crystalline silica and the potential toxicity of crystalline silica, not whether it sits on the list and in what name it is referred to on the list. Am I correct on that assumption or not?

Marc Baril

Normally, yes, if you've got the CAS number on crystalline silica. It didn't happen, it didn't have a CAS number on it. Crystalline silica is the generic name for four, five or six different products mixed together. Crystalline silica is the generic name for a family of products so you have to do the breakdown—you've got no choice.

Neil Murray

So you're using the list as an identification of CAS numbers and the CAS number of the toxicology.

Marc Baril

We have to be linked with something. The sole link with WHMIS is the CAS number in terms of concentration or component.

Peter Robson

I'd agree with the premise that Neil proposed that the purpose of the Ingredient Disclosure List would only kick in at the point that

Peter Robson *continued*

you had a controlled product and you were trying to figure out what you had to disclose in the Hazardous Ingredients section of the MSDS—that's its sole function. There's some kind of cloudiness appearing around the chemistry of crystalline silica. In this example, it was described as crystalline silica. If we'd said quartz, I believe the approach would be that we have to classify quartz on the toxicity data and make a decision on that and then we'd look at the Ingredient Disclosure List. I believe that the Ingredient Disclosure List, in a sense, is a red herring in this one; it's just a means of trying to decide on the chemistry.

Ugis Bickis

My question also deals with the Ingredient Disclosure List despite realizing that we're not to use that list for classification purposes. The question relates to some substances in the list having been assigned a 0.1% cut-off by concentrations and some substances a 1% cut-off. Presumably, there is some consideration, some rationalization that went into that process and that process involved consideration of toxicity.

My questions relate to that. Is there any documentation available of that process? It would certainly facilitate the kind of classification exercise we went through this morning and would facilitate the work for CCOHS.

There's one pair of ingredients in particular that intrigue me. If we look at 1,1,1-trichloroethane and 1,1,2-trichloroethane, the 1,1,1 or methyl chloroform would generally be recognized as a much less toxic solvent. If we commit the cardinal sin of hygiene and bianalogy referred to in the TLVs, we see that the TLV ratio would substantiate that consideration, yet the 1,1,1 has a 0.1% cut-off. I'm wondering if anyone on the panel knows the rationale for that. And can we, as a rule, assume for purposes of a short cut classification that anything in the Ingredient Disclosure List with a 0.1% cut-off would meet a very toxic classification?

Robert Whiting

The criteria for the Ingredient Disclosure List are set out in the original report of the WHMIS Steering Committee in which an industry/labour committee established criteria as to what sorts of health effects would be considered in developing the 1% and the 0.1% list. More specifically, in the 0.1% list consideration of a potential for carcinogenicity, mutagenicity both reproductive or

Robert Whiting *continued*

in vivo, respiratory sensitization and reproductive effects. The intent of the list was not to find chemicals which definitely would be classified as having those effects, but chemicals which were suspected either on the basis of limited data or on the basis of family relationships in the absence of better data.

Some of the chemicals on the 1% or 0.1% list definitely have those effects—definitely have toxic effects and are included in the criteria. Many chemicals on the Ingredient Disclosure List, if classified rigorously, would not have the effects. In fact, some chemicals on the Ingredient Disclosure List, if classified rigorously, would probably not be regarded as hazardous materials at all.

There was some concern, for example, about a substance such as 1,1,1-trichloroethane. I doubt it had anything to do with respiratory sensitization—probably a concern of a possible reproductive effect or a possible carcinogenic effect since it has an IARC monograph. It's only the question that there was some sort of doubt or potential that meant that people were concerned about this chemical or might be concerned about this chemical.

I think there's a possibility in the future that the Ingredient Disclosure List might be refined, but there's no legal process for that. The Ingredient Disclosure List is a legal document, part of the regulation and as such, under current conditions, it serves strictly and only for purposes of disclosure and not for purposes of deciding whether you're going to classify a material or not. You might want to say, "if it's on the 0.1% list, it might be a good idea just to look carefully at what the data is", otherwise, no.

Ugis Bickis

There isn't a listing of, for example: this is 0.1% because of the following considerations and this is 1% because of it.

Robert Whiting

No. In fact, the decision was that we would not link chemicals to suspected health effects because that would tend to tar them; they exist simply as cut-offs.

Ugis Bickis

If I may just make another point on the quartz and the logic versus law issue. In the example that was raised earlier, what if all of

Ugis Bickis *continued*

that quartz were present but at a particle size greater than 10 microns? In other words, none of that quartz was respirable. By law, it would still have to be disclosed, but even in the worst case scenario, there wouldn't be any health effect. Is there any particular way you could deal with it to eliminate the need for labelling?

David Gaylor

The panel decided that crystalline silica might be classifiable because it has known chronic toxicity. If the case was that all of the crystalline silica was in a non-respirable form, then we could use our professional judgment to say that there is no data to link that kind of material to chronic toxicity and not classify it. I think that's the way I would treat it.

Marc Baril

I think that was a good response, David. You have to make a difference between the classification itself and what you mention on your MSDS—it's really important.

Louis Hamel

I have a question that may seem highly hypothetical, but we've been faced with that kind of question since the data in the literature is not always given. Let's say you have a mixture of products and you are considering acute toxicity; you know you've got all the data except one to make your calculation. Your scientific judgment, because the product has been around for a long time or because nobody has tested it, is that it is not toxic in terms of the regulation. But there is another ingredient that is above 1% that would make your product a controlled product because another article of the law says that when you don't know all the data, you have to classify it to control your products. If I exert a scientific judgment, my calculation would give me a non-controlled product, but if I look at the regulation and say, "I've got an ingredient there that is above 1% and I don't have all the data then my product will be controlled." What do I do in such a case?

Peter Robson

It seems to me that this method of calculating LD_{50} and LC_{50} was lifted from the Transportation of Dangerous Goods. The reason it's in was to provide consistency which has been an important

Peter Robson *continued*

feature all along. The TDG has the same rule: you have to know if it's present at or above 1% for each ingredient, you must know the LD_{50} or the LC_{50} value—if you don't then you can't use the formula. It seems to me that it's black and white. If it was commercially important to you to back up your hunch that this missing ingredient has a very high LD_{50} and the consequence would be that the mixture calculation would be outside the scope of WHMIS, you probably could justify doing the test for that ingredient. That seems to me your only way to meet the letter and the spirit of the regulations.

Louis Hamel

There is an article in the regulation which says that we can base our judgment on similar products. Let's say you've got a high polymer and the molecular weight is different enough to make a different CAS number on it. At this point, you have a basis to make a judgment that it won't be lethal.

Peter Robson

As soon as you mention polymer, the rules sort of change. For high polymers that are free of low monomers, the general feeling is that these don't present any significant workplace hazard so the LD_{50} values are always very high. I'd be quite sympathetic with the idea that you could say, "this polymer is so much like these other polymers in this range and the LD_{50}s are all up to 5 grams per kilogram that we're quite prepared to stand behind our position that the LD_{50} for this polymer is also in that bracket." I could probably justify that technically if I was challenged, but I don't lecture that the regulations permit it.

Classification of Imports from USA and EEC

Presenter: David Gaylor
Chairman: Richard Morris

To reclassify products received from Europe or from the US, it is useful to understand the classification systems that are used there. I will be presenting a brief summary of the classification systems that are used in Europe and in the US, compare them with the WHMIS classification criteria and highlight the differences. The workshop proceedings will contain a more detailed comparison that you can look at. (Reference paper: Appendix 1—Classification of Imports from USA, EEC)

Although there are many similarities between the classification systems used in Europe and in the US, there are many differences as well. These differences are very important and very significant. They are significant enough that it's going to require you to do a detailed review of the criteria when products are imported. If they haven't been classified under WHMIS, you will have to review how to reclassify these materials.

All of the discussion we've had about professional judgment and justification of classification under WHMIS applies to classification of imports. The classification differences addressed in this presentation include cases where there's fewer criteria, more criteria, different class types, different specified test methods, defined hazard symbols and the approach to classification of mixtures.

OSHA Requirements

Products generated in the US come under the OSHA Hazard Communication Standard which is very similar in scope to WHMIS. There are physical and health hazard definitions which are used to define appropriate label content, MSDS content and worker education—the very same things covered under WHMIS. But it is very much a performance based standard. Our US sister company notes, for example, that the classification system is so performance oriented that it's liability driven. (They don't put anything on their data sheets or their labels without checking it first with their lawyer.) There are suggested references in the OSHA Hazard Communication Standard to direct you to the sources you should use to make your professional judgment.

The only reference in the US to hazard symbols is not in the OSHA Hazard Communication Standard itself. The only place you'll find guidance is in the ANSI Standard on Precautionary Labelling. There you'll find suggested risk phrases and some suggestions on hazard symbols in appendix B of the new ANSI Standard. But there

David Gaylor *continued*

is only one mandatory symbol and that's the skull and crossbones for the highly toxic class. Basically the OSHA Standard does not require hazard symbols—the ANSI Standard recommends only one and discourages the use of any that are not well recognized.

Major differences between OSHA and WHMIS

The LC_{50} criteria for acute lethality is a much lower number than under WHMIS. This is because the LC_{50} criteria under WHMIS was made consistent with the TDG criteria. There are no specific criteria for chronic effects, reproductive effects or teratogenicity, but there are target organ classifications which must consider these kind of health effects. Under the carcinogenicity class, the OSHA Hazard Communication Standard considers IARCs groups 1 and 2 the same as WHMIS, but also considers the National Toxicology Program (NTP) carcinogens and any carcinogens that are listed under OSHA.

Also, any single positive animal study showing evidence of carcinogenicity must be identified under OSHA. That's important for products such as polyethylene. Since polyethylene has caused tumors when it was applied in subcutaneous tests in animal studies, it could be identified as a carcinogen in the US but it wouldn't be in Canada under WHMIS.

Not classified under OSHA are: mutagens, although this effect may be considered under the reproductive target organ toxic effects; biohazardous infectious materials or dangerously reactive materials.

There are additional hazard information requirements under OSHA. Under the carcinogenicity classification or any of the target organ effects one positive animal study or any evidence of an effect in humans is enough to classify the product. Lung irritants are specifically considered under OSHA as a target organ effect. Lung damage caused by any of the pneumoconiosis causing dusts such as silica is also easily caught by OSHA as a target organ effect. Under WHMIS, lung irritants are not mentioned and chronic toxic effects are related to specific doses in animal studies. If you recall the earlier discussion on example 2, the consensus was easily reached that definite human evidence of chronic toxic effects such as those caused by silica exposure would be considered to meet the WHMIS chronic toxic effect criteria. Because any positive animal study of statistical significance is reportable under OSHA, you're likely to find the US MSDS contains much more toxicological data which may or may not affect the WHMIS classification.

David Gaylor *continued*

There are very few tests specified under the OSHA Hazard Communication Standard. We had a very good description of the types of irritant tests and scales that are used under OSHA this morning. The acute lethality inhalation tests that are specified under WHMIS are one hour not four hours. Explosives are classified under OSHA, but are not yet under WHMIS.

For classification of mixtures there is very similar approach but again some important differences. In OSHA there are 1% and 0.1% cut-offs; the 0.1% cut-off applies only to carcinogens. In WHMIS, it also applies to reproductive toxins, lung sensitizers, teratogens and very toxic mutagens, so many more classifications under WHMIS than in the US are considered more hazardous with a corresponding low cut-off concentration of 0.1%.

The cut-off concentrations can be less than 0.1% or 1% if components can be released and exceed the OSHA Permissible Exposure Limit or cause a health hazard to employees when they're used. Another important difference is that under WHMIS, it's very much implied that you have to document your health hazard evaluation procedure, (if you don't, you'll be in trouble if you're challenged), but it's actually a written requirement under OSHA.

EEC Requirements

The regulations in Europe have been around a lot longer than they have in the US and Canada. There are no EEC MSDS requirements in Europe although they do exist and some countries have a general requirement for MSDS production. Classification is mostly for the purpose of labelling so combinations of risk phrases, hazard symbols and safety advice phrases are all specified. In fact, an Annex to the EEC Directive actually classifies a great number of chemical agents and specifies the precise label content. There is some professional judgment required in applying the criterion and deciding which combination of hazard symbol and risk phrase to use where classifications are not assigned.

A very complex handling of preparations is used compared with the cut-off concentration rules imposed by WHMIS.

Major differences between EEC Directives and WHMIS

Reviewing the criteria differences—flammability—the flash point ranges are different although the highly flammable and extremely flammable classifications in Europe are totally within the flammable range defined by WHMIS.

David Gaylor *continued*

Acute lethality—the LD_{50} and LC_{50} ranges are all different, although some ranges completely fall within some of the WHMIS criteria. Other serious acute effects are also cited—acute effects that are encountered at doses less than fatal doses when acute toxicity testing is performed. This criterion is not specifically included in the WHMIS Controlled Products Regulations.

The chronic effects specified doses are different than the WHMIS classified doses.

Carcinogenicity—the IARC criteria are recognized in Europe, but the list is not specified in Europe as it is in US and Canada. Professional judgment is allowed in classifying IARC Group 1, 2 or 3 materials as very toxic, toxic or harmful.

Respiratory irritants are specifically included in the EEC Directive but not in WHMIS.

Not classified in Europe are Compressed Gases, reproductive toxicity. The definition of their toxic effects, and biohazardous infectious materials is unique to Canada. Compressed gases and biohazardous infectious materials are only included in transport regulations in Europe at the present time.

Additional classifications—under the EEC Directive include Explosives and a Harmful class which overlaps several of the WHMIS classification criteria including chronic toxic effects, mutagenicity, carcinogenicity, acute lethality and respiratory tract sensitization.

Although similar for most of the classes, there are different hazard symbols from those specified by WHMIS in Europe for the Irritant, Harmful and Explosive classes. The skull and crossbones is used in Europe a little differently than it's used in Canada so you can't automatically classify your material based on that. The colour and size of hazard symbols is specified in the EEC Directive. You will see in later slides the colour to be an orange yellow background with black outline.

I mentioned the classification of mixtures in Europe as being a quite complex process under a proposed preparations directive. This proposed directive is modelled after two sets of regulations already in place: one for solvents and one for paints, varnishes, adhesives, printing inks and similar materials. There is an Annex to these preparation directives classifying a number of materials.

David Gaylor *continued*

Proposed regulation uses the same rules as applied in the solvent and paints regulations. They've assigned an index to different chemicals and depending on the percent weight and the sum of the product of that percent weight and those toxic indices, the material will be classified as very toxic, toxic or harmful.

There are concentration limits specified and they're used to classify corrosives or irritants, products with non-lethal irreversible acute effects, chronic effects, carcinogens, mutagens and teratogens. Corrosives, irritants and combinations of corrosives and irritants are additive. Cut-off concentrations employed are higher for these types of effects than specified under WHMIS (ie 10% or more compared to 1% under WHMIS). Appendix 1 provides a detailed summary of the WHMIS classification criteria compared with criteria specified in the US and Europe (reference Appendix 1).

Compressed gases are not classified in Europe under EEC. The OSHA criteria are basically the same as WHMIS except the critical temperature and absolute vapour pressure aren't specified the same way as in WHMIS.

Flammable gases—the symbol in EEC and WHMIS is very similar, but allowed colours on WHMIS symbols are different than the orange colour specified in the EEC. Flammable concentration ranges aren't specified in the EEC; OSHA and WHMIS are the same.

Flammable liquids—under EEC you can have either extremely flammable liquid or highly flammable liquid designations and they would get the same symbol. The difference is that the concentration ranges for extremely flammable materials have flash points < 0°C and highly flammable materials have flash points between 0°C and 21°C. Although those flash point ranges are different, if it was extremely flammable or flammable in EEC, it would be a flammable liquid in Canada. Under OSHA, criteria are basically the same as WHMIS.

Combustible liquids are the same in WHMIS and OSHA. There is a flammable class in Europe which overlaps part of the range; it goes up to 55°C—that's not quite as high as the combustible liquid range under WHMIS.

Flammable solids—basically, the EEC and WHMIS criteria are very similar. The difference is that in OSHA if a material caused fire from absorption of moisture or spontaneous chemical change,

David Gaylor *continued*

it would be classified as a flammable solid—under WHMIS, that's reactive flammable. They've included a part of our reactive flammable class in their flammable solid class. Under OSHA the flame symbol is acceptable. In Appendix B to the ANSI Standard, there is a report which tried to validate various symbols and they accepted the flammable symbol as one which people would readily recognize although it's not mandated in the Standard itself.

Flammable aerosols are covered under a different regulation entirely in the EEC. The criteria are different from those in WHMIS and OSHA which are the same; you label something flammable or give it a flammable symbol, if there's flammable gas or liquid contained at more than 45% or more than 250g under European regulations.

Reactive flammable materials—under OSHA, the reactive flammable criterion is included under flammable solids. The EEC and WHMIS criteria are about the same.

Oxidizing materials—are basically the same in WHMIS, OSHA and EEC except that in the US organic peroxides are classified completely separately. If it's an organic peroxide in the US then obviously it would be an oxidizing material in Canada. In Europe, there is one additional criterion– if it's explosive when mixed with a combustible material, then it's also called oxidizing.

Acute lethality—the differences here are not as much as you might think. As I mentioned before, under EEC the oral and dermal LD_{50}s are different ranges. For example, the oral LD_{50} is less than 25 mg/kg LD_{50} in Europe and under WHMIS, it's less than 50 mg/kg. OSHA and WHMIS are the same for oral and dermal toxicity, but different for inhalation. When you get materials from EEC countries or the US, you will have to consider these differences.

The WHMIS acute lethality toxic classification criteria are different as well. For instance, under WHMIS, the specified oral LD_{50} is a range from 50-500 mg/kg; under EEC, it's 25-200 mg/kg. If the oral LD_{50} happened to be greater than 25 mg/kg and less than 50 mg/kg the material would be very toxic in Canada, and toxic in Europe. The specified inhalation concentrations are also different in OSHA, WHMIS and the EEC Directive.

Still under acute lethality—EEC has another class called Harmful that has some overlap with the toxic classifications under OSHA

David Gaylor *continued*

and WHMIS; depending on where the LD_{50} lies, you might classify it as toxic here or not at all.

Chronic toxic effects—under OSHA, all chronic toxic effects are considered when you examine effects on target organs. You would have to review the data that you get on a data sheet or whatever material you received on a product from the US to see whether the information would meet the WHMIS criteria. A judgment and reclassification process is necessary.

In Europe, there are no numbers stipulated for chronic toxic effects, at least none that would match the very toxic criteria. What they do say is that if there are serious effects at doses much less than what they consider a harmful class dose then you would consider it toxic—not very toxic. How much different or how much less than the harmful doses, we don't know—judgment again.

Chronic toxic effects—the WHMIS toxic class is comparable to OSHA, target organ effects. The scientifically significant animal studies cited under OSHA would have to be compared to WHMIS toxic or very toxic criteria. The EEC Harmful class does specify doses which are different from the chronic doses specified under WHMIS. Again, you'd have to consider what the actual dose was in the cited animal studies.

Teratogenicity and embryotoxicity—again, that's a target organ effect in the US. Basically, EEC and WHMIS criteria are similar under this category.

Carcinogenicity—we talked before about polyethylene being a carcinogen in subcutaneous tests, therefore a possible carcinogen under OSHA, but not under WHMIS since it does not fall under one of the required lists. Under EEC, there's a Harmful class where IARC Group 3 carcinogens may be included. They would not be classified in the US or Canada. There's a bit of a choice in the hazard symbols that are used in the EEC—you could use that Harmful X class or the skull and crossbones depending on which category it fits into. There's some judgment involved again where hazard symbols have not been specified.

Reproductive toxicity—you would consider that under target organ effects in the US. There are no specific criteria in the EEC although it would be considered under the chronic toxic effect class.

Respiratory tract sensitization—basically EEC and WHMIS criteria are the same—only in the EEC it's called Harmful and

David Gaylor *continued*

in WHMIS it's Very Toxic. Under OSHA, both lung and skin sensitizers are included in a sensitizer class.

Mutagenicity—there are similarities between EEC and WHMIS although there's some judgment in which classification you would use—in Europe either toxic or very toxic. Under OSHA, not classified—you may even get some MSDSs that quote Ames tests which, of course, don't fall under WHMIS classification at all. The WHMIS criteria considers only in vivo animal studies and not bacteria tests.

Mutagenicity—the toxic class under WHMIS is similar to the EEC Harmful class although EEC category 3 evidence isn't satisfactory to classify it as a mutagen in Canada. Under OSHA, mutagens are not classified, although you will certainly see mention of mutagenic effects as reproductive target organ effects.

Skin and eye irritation was covered very well this morning by Richard. To review both the EEC Directive and WHMIS, use the OECD Test Guidelines. OSHA uses a modified Draize scale for skin irritancy and a little more complex process for classifying a substance as an eye irritant. Under OSHA, they not only have skin and eye irritant classifications, but also lung irritants. Respiratory irritants are also included in the EEC but not specifically under WHMIS.

Skin sensitization—EEC and WHMIS are basically the same. Skin sensitizers are in the sensitizer class under OSHA. Cut-off concentrations for preparations in the EEC would be greater than the 1% specification in WHMIS.

Biohazardous infectious material—the classification is unique to WHMIS.

Corrosivity—the corrosivity criteria are very similar except that in Canada, compounds that are corrosive to metal or corrosive gases are also specifically included as corrosive materials. OSHA excludes inanimate objects such as metals. There's no mention of metals in the EEC although their hazard symbol seems to indicate that they considered it.

Explosive materials are classified under OSHA and EEC and not under WHMIS.

Dangerously-reactive materials are not classified under OSHA. Although there's no hazard symbol specified in the EEC, there

David Gaylor *continued*

are risk phrases or criteria very similar to WHMIS criteria that would fall under the dangerously reactive class.

I want to emphasize that there are very important differences between the OSHA Hazard Communication Standard criteria and the WHMIS criteria and between the EEC Directive criteria and the WHMIS criteria.

It would be ideal to have the materials that you are importing classified by your supplier, but you're likely going to have to do it yourself. You have to recognize that there are very few directly equivalent classifications although there are some similarities. Sufficient formulation data will be required to classify your materials that come as imports. It's going to be a little more difficult if your product comes from Europe because there are no specifications for the MSDS; the MSDS from Europe tends to have a lot less information than the ones in North America. You may have more luck with products that come from the US because their MSDSs will probably have more information than ours do for liability reasons. Under the OSHA Hazard Communication Standard, there is a requirement to document the health hazard assessment. If you were in the US, you would have access to that information if you challenged the classification. You may not be as lucky in Canada in getting that kind of assessment from your supplier in the US, but it would make the reclassification under WHMIS a lot easier.

Paul Arsenault
Lake Ontario Steel Co Ltd

It was my understanding that, as a condition of sale, manufacturing, supplying or importing, the supplier had to confirm or abide by the WHMIS standard set out. Are you now you're saying that it's up to us?

David Gaylor

Under WHMIS, the actual wording is that the importer is responsible for the classification. If she/he gets that classification from the supplier, that's great, but the importer is responsible for the classification, the MSDS and the label.

Robert Dell
Dell Tech Laboratories Ltd

It seems to me, at least at the front end of this legislation, there's going to be a tremendous duplication of effort. I get this image of 1,000 chemists across this country trying to look over mutagenetic studies of chloroform. I think we all have an obligation to try and get back to the CCOHS resource base with some of this information to help each other out. I don't see why hundreds of people need to duplicate it. I hope we can share some of this information with each other.

David Gaylor

I think that's an excellent comment. If it hadn't been made today, we were going to bring it up ourselves because there's considerable effort from all of us in industry in classifying our materials. Some form of co-operation through CCOHS and amongst ourselves is something which I believe would be a very good thing.

John Harrison

If I was to import something into the country from Europe or the States and use it in my own workplace, I don't need a supplier label; I just need to put a workplace label on it? Am I right?

David Gaylor

No, that isn't correct. You'd have to have a supplier label on it, even if you're going to use it in your own workplace because you're still classified as an importer whether you resell it or use it yourself.

Gerald Gough

I can't agree with that statement. As far as I'm concerned, the Hazardous Products Act and the Controlled Products Regulations refer to the sale of a product from a supplier or importer to a customer. If you're bringing it directly into your own workplace, you're not selling that product—you may be importing, but you're not selling so you're not subject to the Controlled Products Regulations—you're subject to the workplace regulations.

Peter Robson

I think that there probably is confusion. I have a suggestion. I think that the definition of sale in the Hazardous Products Act is not just sale, it covers import. That's spelled out in the Act.

Peter Robson *continued*

Brian Connell is knowledgable about the regulations and perhaps he would be willing to offer us some guidance. Brian Connell is from the New Brunswick Occupational Health and Safety Commission and has been involved in the regulatory team developing the regulations and refining them.

Brian Connell
New Brunswick Occupational Health and Safety Commission

Thank you Peter. I hadn't really come prepared to comment in any way; I came to listen to the dilemmas and issues related to the implementation of the WHMIS legislation both at the federal and provincial levels.

We've discussed this as we've gone through the development of the model OSH document. It is true that the definition of the federal legislation with respect to supplier does embrace distribution in addition to sale. If you look at the model OSH document, you'll see that there are obligations on the employer who receives an imported product that would be classified under the Hazardous Products Act and the Controlled Products Regulations. I think a workplace label would be appropriate.

The workplace label is different from the supplier label, but the employer would have all of the obligations to develop a MSDS for the imported product. The model OSH document does say that the material will be identified, that there will be hazard statements and there will be reference to a MSDS, if any, which takes into consideration some other products that are normal consumer products and may find their way to the workplace.

With respect to the importation, the federal criteria and the federal law have to be considered by the employer whether as a supplier or simply an employer. In New Brunswick, we expect at least a workplace label on those products. My understanding is that a workplace label would be sufficient in that situation, but the MSDS requirements would have to be complied with as well. Each of the jurisdictions will be enforcing the federal legislation—there will not be federal inspectors. The determination in the jurisdiction will be germane to the compliance question.

Myra Plotnick

When you were showing the different classification criteria underneath the "T" symbol, you had Class D, Division 2. Was

Myra Plotnick *continued*

this done to illustrate a point or was this actually mandated? After you classify something, is it enough to put the "T" symbol on the label, or do you have to put the divisions and the class underneath the symbol?

David Gaylor

If I were labelling a product, I would use the "T" symbol with either the toxic or very toxic classifications as you saw this morning in Geoff's slides. This was just for illustration purposes to exactly identify the criteria. You could choose not to write anything underneath it, but I would add either very toxic or toxic instead of Class D, Division 2. This is not mandated at all.

Guy Ethier

I have a question for David. It's been said a couple of times and you mentioned that in the US there's a question concerning liability and telling everything you know about a product on a MSDS. Some of you mentioned that if we knew something about a product even though it was not relevant, we would still have to put a risk phrase about that component. I would like to know if that's true or not or was I misinterpreting what I heard this morning?

David Gaylor

For the purposes of classification, it's not required to know something about the product. But for the purpose of a MSDS or a label, if you happen to know something about a product then it is incumbent upon you to inform people; but it doesn't really have to do specifically with the classification of the product.

Guy Ethier

My question is specifically related to the components. If I knew something about a component which is totally irrelevant to the product, do I have to report what I know about the component on a risk phrase? For example, benzene in gasoline.

David Gaylor

I think your risk phrases should apply to the product and not to the components. The properties of a component may affect the risk phrase that you use, but it's the properties of the product that you're considering in developing your warning statements.

Geoff Granville

If you have more than 0.1% benzene in gasoline—benzene is a controlled product—it is then incumbent upon you to communicate the hazards of benzene. If you happen to have 0.05% benzene in gasoline then it becomes your decision. If you meet the controlled product requirements, you're driven by the system; if you don't, you can exercise judgment.

Guy Ethier

In terms of risk phrases...

Geoff Granville

Risk phrases—the same again. If you have more than 0.1% benzene, you must communicate that aspect.

Guy Ethier

That it contains more than 0.1% benzene or that there's greater risk to benzene at more than 0.1%?

Geoff Granville

The content of the risk phrase is not mandated so it's your choice what you want to say, but you will make an appropriate risk phrase.

Roman Kostiuk

I have a question for David regarding importation of controlled products from countries such as Europe and the US. Do the WHMIS labels have to be already affixed on the products before they enter Canada or can they be affixed at their first destination before they are distributed to the customer?

David Gaylor

My understanding is that they can be affixed at the first destination. They don't have to come with the labels, but there are requirements for notification when you're importing.

Roman Kostiuk

This brings us back to the previous question asked by John Harrison of LePage's about whether or not a WHMIS label has to be on his product when he uses it internally. If you don't have to have

Roman Kostiuk *continued*

the WHMIS label for imports from the US into Canada, you can accept the product in your workplace and then put on your own workplace label.

David Gaylor

That was the interpretation of New Brunswick; it's province dependent.

Fayek Kelada
Province of Saskatchewan

Related to importation, it appears clear to me from the definition of a supplier in the Hazardous Products Act that "a supplier is a person who, in the course of business imports or sales"; that "imports or sales" means if she/he brings it for his/her own use, she/he still imports it and therefore, she/he is a supplier. Therefore, I don't agree with Brian Connell that the workplace label which should be attached should be a supplier label and should go through the whole thing.

I have a question for Richard. I'm concerned about the dilution effect—things that are not controlled that have to be included as a controlled product not because of anything other than because the regulations are not rigid enough. For example, the question of 5% silica in the form of dough where the silica does not pose any risk to the workers or the question of a 1% skin irritant which may not be a skin irritant. This will carry the same "T" symbol as a carcinogen. It sounds to me as if we are diluting the effect of WHMIS this way by including chemicals by default or because of the non-specificity of the regulations.

An example is flour. Flour causes baker's asthma; that's why it's a sensitizer. In a concentration of more than 0.1%, it classifies a whole product into a controlled product although the flour is in the form of a dough, paste, or liquid; it does not pose any lung sensitization risk in that form.

Another example are LD_{50}s you get from the RTECS for something that is very innocuous. We find that among the LD_{50}s there is wide variation of species. A specific example is potassium chloride, such as in potash from the ground. Potassium chloride has an LD_{50} of 2,600 in rats but 336 mg/m3 by oral administration to mice. If you classified as a hazardous product, you are diluting the effects of WHMIS. Can we prevent this dilution effect on WHMIS?

Brian Connell

The model OSH regulation states that where a controlled product imported under Section 23 of the Controlled Products Regulations is received at a place of employment without a supplier label, the employer shall affix a label that meets the requirements of the Controlled Products Regulations. I think that's clear.

If the product is going to be redistributed downstream, it is clear that a supplier label needs to be affixed to it. If it's in the workplace, you can look at it either way. I think Quebec is probably fair to say a supplier label; the other jurisdictions may say that a workplace label would be fine. This will be clarified by the development of a policy document on OSH that all of the jurisdictions will agree to, we're in the process of developing that now and that information will be communicated. But in essence, the label that's produced in the workplace could satisfy the regulators in that province. That's an issue between the regulatory agency and the employer, if that product is being imported and being used in that workplace. The words in the model OSH document a supplier label would be required.

Richard Morris

Thank you for that clarification Brian. I agree that there are grey areas. I don't think we want to see bags of flour with "T" symbols on them. At the same time, I don't agree that putting these Ts on legitimate products is going to dilute the effects. I don't think seeing a T should represent to a worker (and this comes down to education), a potential carcinogen or a mutagen. One of the justifications for buying into a symbol, other than the skull and crossbones to deal with other toxic effects, was to deal with this whole issue of what message you're conveying to the worker.

What we were hoping the symbol would do is say to the worker: "This product may have certain toxic effects—go to the MSDS and find out what they are—maybe you should be taking some sort of precaution. If it's a one time use and all that is mentioned is chronic effects, you know how to deal with that; if it has acute effects that you need to know about, you expect it to have a skull and crossbones".

There was validity to a somewhat late effort on the part of industry and other members in the WHMIS process coming up with a different symbol to differentiate between acute toxic and the other toxic concerns. Some points will have to be dealt with through the education process itself, and part of it is going to be just the

Richard Morris *continued*

experience of getting this thing up and running. I think we're bound to see some problems along the way and we'll have to solve them one after the other.

Joey Stewart
Esso Resources Canada Ltd

David, I wanted to ask you about importation. Do you know what is happening in the Pacific Rim countries in respect to hazardous materials?

David Gaylor

No, I don't. I had trouble enough figuring out what was going on in Europe and the USA. Perhaps somebody else could address that.

Geoff Granville

Japan has had for at least 10 years a form of communication system; that's the only country in the Pacific Rim which has specifically done one. It's very difficult to get good details. You know what products are covered, but that's about all you know.

Susan Anderson
Agriculture Canada

I work in a pathology laboratory. The WHMIS regulations as far as the chemicals are concerned seem to spell out very clearly the classifications specifying MSDSs. What about Class D of Division 3—Biohazardous Infectious Material section—is there going to be legislation in the future spelling out classifications more clearly? Should we be thinking of MSDSs for our bacterial cultures?

David Gaylor

Biohazardous infectious materials are covered under WHMIS. The problem is that the criteria are not very well defined. I suppose you have to use a lot more judgment there than you would use in some of the other classifications. There's no question that they are covered under WHMIS; you would require a MSDS and label. It's a matter of interpreting the one short paragraph under Biohazardous Infectious Material; none of us really touched it because we really don't know what it means either.

Peter Robson

This set of criteria for Biohazardous Infectious Material is essentially an identical copy of what's in the Transportation of Dangerous Goods Regulations so there is some precedent. If you don't shift them, then TDG doesn't apply. I've talked to a few organizations which handle them. It seems that in the business of handling infectious micro-organisms, there is some technical basis for deciding which are and which aren't infectious and there are also the criteria that involve the toxins that these may produce. There are no specific dose-related criteria or specific test results; I'm sure that's going to be a technical judgment. It may be that people who are in that business may decide that they want to develop some guidelines as to where to draw the line. My guess is that those guidelines probably already exist for other reasons.

Richard Morris

Schedule 7 of the TDG Regulations actually provides a list of infectious organisms such as bacteria and viruses. It's not very up-to-date; for example, it doesn't have AIDS on it; I think the last thing it had on it was Bioengineered DNA. It is certainly a guide, but it's not the total answer.

Susan Anderson

So in other words we should work on the assumption that if we at least make up some sort of MSDS for these organisms we'll be covered.

Richard Morris

Yes.

Gerald Masters
Helmitin Canada Inc

I'm a bit confused about the MSDSs as far as importing products. From what I've heard, for every safety data sheet we get for anything we bring in from the States, we have to re-write that ourselves for our plant people—in other words, have another copy written that follows specifically the WHMIS system if the one in the States doesn't exactly. There are two problems with that: Aren't the data sheets from the States considered good enough as they are used? If, for example, it comes in proprietary ester formulation and we don't have enough data from their data sheet to fill out our own data sheet, then do we now have to classify everything

Gerald Masters *continued*

as acutely toxic and radioactive because we're given a proprietary ester formula and we don't know what it is?

David Gaylor

That's a very good question. The answer to the first part is the data sheets that come from the US, if they're meeting the OSHA Hazard Communication Standard, are very good although there are some requirements under WHMIS that aren't specifically required in their MSDSs and vice versa. Yes, you do have to do a revision, but probably not a very big one.

The second part of your question has to do with proprietary information in the States and that's a bigger problem. That's something you have to work out between you and your supplier because you're really stuck with that one. If you have proprietary information on your data sheet and that component is a controlled product and you don't know it, that presents a very big problem for you that you'll have to sort out with your supplier. I don't know how to address that other than to develop a pretty good relationship with your supplier.

Try a standard letter to all your suppliers telling them about WHMIS—about five years ago, when we were all asking for MSDSs, it didn't work very well, but I suppose we could try.

Yves Billoux
Michelin Tires

I suggest that your relationship with your supplier might quickly deteriorate if you asked them to reveal their trade secrets in Canada.

David Gaylor

That may be the case. But if you make them aware that to use their product in Canada you have to meet the WHMIS classification criteria or at least know whether the product meets it, that might be an economic lever for you. You could say, "I can't use it unless you tell me what the classification is—don't tell me what the trade secret is, but classify it for me." I guess that's about the best approach you could use.

Peter Robson

I think that's a very important issue and it's going to affect a lot of us that import products from the US with trade secret

Peter Robson *continued*

involvement. One thought that occurred to me is that a US supplier who owns the trade secret is obviously not willing to disclose it. You as the importer are legally required by the federal regulations to register that as a valid trade secret. One practical way of dealing with this would be to advise your US supplier of the WHMIS requirements that we cannot just claim it as trade secret without the blessing of the Trade Commission in Ottawa, and then have the US supplier contact the Trade Commission through a Canadian agent such as a lawyer's office. Now you have a Canadian contact which the federal government needs and then they can disclose their information in confidence to the Trade Commission and take care of the legalities without having disclosed their trade secret to their customers.

Richard Morris

I assume Peter when you're referring to the Trade Commission, you mean the Hazardous Materials Information Review Committee.

Peter Robson

Yes.

Neil Murray

My question refers back to the classification of Material 1. Bob, if I read you right, your classification of the material was based to some extent on chloroform as a very toxic material; that there were some reproductive data available would not be used to move you to classification. I think the comment was made that you would want to alert people to the fact that the chloroform potentially could cause some reproductive effects. Am I reading you right on that?

Robert Whiting

Yes, it's perhaps getting beyond the classification idea, but the WHMIS data sheet requires information to be given about various aspects of the hazard that the product might have including reproductive effects. Even if you have a reproductive effect which does not meet the criteria, it would most often be in your interest and the worker's interest to say that that information existed. That's really quite a separate issue from classifying.

Neil Murray

I appreciate that. I raise this because of the question on benzene; obviously it all ties into the question of whether it is above the concentration cut-off or not. If the chloroform was 2% rather than 20%, would you feel the same urge to disclose?

Robert Whiting

Since you have to fill in a piece of information on the MSDS about the possible reproductive effects of a product, I think you would want to convey, through the use of the words you chose, whether this was a small or a large risk or whether there was limited or substantial evidence.

Neil Murray

I think that some of the concerns throughout this workshop have been over developing undue anxiety. I guess this is one that's going to continue to be debated for some time.

Charles Kennedy

If we have two toxic products A and B and you mix them to get product C, should we apply WHMIS? If yes, how? If not, why?

David Gaylor

You would have to consider classifying it, yes, but based on the properties of this new material. If you didn't know anything about it, then it's not classifiable, I suppose, but you'd still have to try to classify it based on what you knew about the reacted material. Do you have a specific example?

Charles Kennedy

For example, when we mix epoxy with toluene to get a new product, we have to identify this product to know what this product is. Do we have to apply WHMIS? It is not easy because we cannot make an identification.

David Gaylor

I agree if you're mixing two materials to produce a third completely different material that you don't know anything about, it would be difficult to classify. But if you're in the business of doing that, you probably do know something about that product.

Closing remarks

Lillian Vine

Thank you very much. At the beginning you agreed that there were some complexities and that a lot of issues were not going to be settled for some time. I think, at the end of the day, that has certainly been confirmed.

Geoff and Peter were the requesters of this workshop. One of the issues which concerned them a great deal has been raised again and again and that's the issue of consistency. I'm going to call on Geoff for the last word. I just want to say that it was a great pleasure having you here. We will get to work on these proceedings immediately.

Geoff Granville

Just to give a quick summary of today, the first and the last thing we mentioned is professional judgment required all over the place. There is not, as you heard, consistency with respect to imports between WHMIS and EEC and US regulations. We know that articles are not as simple to classify as we originally thought. We know that exposure is generally not mentioned except implicitly; it is mentioned once for articles. Yet we know it comes into focus every time we talk about human effects.

Given all those factors, we have a potential problem of inconsistencies in the classification process. There's also going to be a lot of duplication of effort in developing categorization and classification of WHMIS controlled products. So how do we minimize all that? There's no one easy answer, but there are some things I hope you take away from this discussion.

With respect to industry associations and industry sectors, I think you should start to think how to get your industry sectors together to try to avoid inconsistencies; you should examine how to go through paints and coatings, how to go through organic chemicals, how to go through petroleum products; and you should try to develop first draft guidelines and then firm guidelines on how to consistently classify major products.

Then we can look at CCOHS as a clearinghouse. It already has quite a large data base to do that. One can look at standards from other organizations. But in this instance, it's probably not appropriate—industry and CCOHS are likely all you need. I'd like to end up on a positive note rather than saying "oh my gosh, this is terrible." Most base chemicals we're handling, most commodity products—there are only about 1,000 of them. They are

Geoff Granville *continued*

manufactured and distributed by relatively few major companies, and that's where the expertise is. When it comes to base materials, there may be a problem getting them classified consistently but it will be done. It's going to get done in the next six to nine months and I hope we can do it with a minimal amount of inconsistency.

Once that's done, the mixtures and the other products that flow out of that should be a lot easier to classify in the workplace and to suppliers. I think we should be going through this agony now because it's time for us to understand what was meant by WHMIS. Once we go through that and get down to some practical work, it'll become easier, and in a year we shouldn't have these great problems. But be aware, there's going to be a lot of work to do in the next six to nine months. I hope you can all go away thinking about how to develop consistency. Industry associations and a lot more awareness from this type of session are needed to do that.

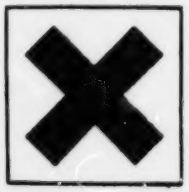
I'd like to thank the Canadian Centre very much for setting up this workshop. It's been a pleasure to be here and enjoyable to have these conversations and discussions with everybody. From where I'm sitting, it's been a very successful workshop. If I can speak for Peter as well, I'd like to say we both had high expectations when we came in and I think they've been met. I don't feel any better—I've got more problems now than I had when I walked into this session, but at least they've been discussed and there will be fewer surprises. Thank you CCOHS.

Lillian Vine

Thank you for asking us and for sharing your expertise with us. Thank you all for coming.

Appendix 1
Comparison of WHMIS Classification Systems to Those Used in the US and EEC

CLASSIFICATION: TERATOGENICITY, EMBRYOTOXICITY

CPR SECTION 53	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T Xn 
CRITERIA	- SUBDIVISION A, VERY TOXIC - SHOWN TO CAUSE: - DEATH - MALFORMATION - PERMANENT METABOLIC OR PHYSIOLOGICAL DYSFUNCTION - GROWTH RETARDATION - PSYCHOLOGICAL OR BEHAVIORAL ALTERATION DURING PREGNANCY, AT BIRTH, OR IN POSTNATAL PERIOD	- NO CRITERIA SPECIFIED - WOULD BE INCLUDED IN REPRODUCTIVE TOXIN, TARGET ORGAN CATEGORIZATION	- TOXIC, VERY TOXIC CATEGORY 1 (R47) - KNOWN TO BE TERATOGENIC IN MAN - EVIDENCE OF EXPOSURE TO SUBSTANCE AND SUBSEQUENT NON-HERITABLE BIRTH DEFECTS IN OFFSPRING - HARMFUL CATEGORY 2 (R47) - SHOULD BE REGARDED AS IF THEY ARE TERATOGENIC IN MAN

CLASSIFICATION: FLAMMAPLE LIQUID

CPR SECTION 37	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS B, DIVISION 2	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	F F+
CRITERIA	- FLASHPOINT $< 37.8^{\circ}C$ ($100^{\circ}F$)	- SAME AS WHMIS CRITERIA - MIXTURES HAVING COMPONENTS WITH FLASHPOINTS $\geq 100^{\circ}F$ AND COMPRISING $\geq 99\%$ OF THE TOTAL VOLUME WILL NOT BE CLASSED AS FLAMMABLE LIQUIDS	- <u>EXTREMELY FLAMMABLE</u> FLASHPOINT $< 0^{\circ}C$ AND INITIAL BOILING POINT $\leq 35^{\circ}C$ F+, (R12) - <u>HIGHLY FLAMMABLE</u> $0^{\circ}C \leq$ FLASHPOINT $< 21^{\circ}C$ F , (R11)

CLASSIFICATION: EXPLOSIVE MATERIAL

CPR SECTION	WHMIS	OSHA	EEC
HAZARD SYMBOL		- EXPLOSIVE HAZARD SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- NOT CLASSIFIED - COVERED UNDER FEDERAL EXPLOSIVES ACT	- CHEMICAL THAT CAUSES A SUDDEN ALMOST INSTANTANEOUS RELEASE OF PRESSURE, GAS AND HEAT WHEN SUBJECTED TO SUDDEN SHOCK, PRESSURE OR HIGH TEMPERATURE	- RISK OF EXPLOSION BY SHOCK, FRICTION, FIRE OR OTHER SOURCES OF IGNITION (R2) - EXTREME RISK OF EXPLOSION BY SHOCK, FRICTION, FIRE OR OTHER SOURCES OF IGNITION (R3)

CLASSIFICATION: CORROSIVE MATERIAL

CPR SECTION 65	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS E	- HAND CORROSIVE SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	C
CRITERIA	A) CORRODES SAE 1020 STEEL OR 7075-T6 NON-CLAD ALUMINUM AT >6.25 MM/YR AT $55^{\circ}C$ B) CORROSIVE TO SKIN IN ACCORDANCE WITH OECD 404 C) IN CLASS 8, PART III, TDG D GAS IN DIVISION 4, CLASS 2, PART III, TDG E) POSITIVE EVIDENCE OF VISIBLE NECROSIS OF HUMAN SKIN TISSUE F) MEETS (B) & (E) AND PRESENT AT $\geq 1\%$ IN MIXTURES	- CAUSES VISIBLE DESTRUCTION OR IRREVERSIBLE ALTERATIONS IN LIVING TISSUE - SPECIFICALLY DOES NOT INCLUDE CORROSIVE ACTION ON INANIMATE SURFACES	- CAUSES SEVERE BURNS (R35) - FULL THICKNESS DESTRUCTION OF SKIN TISSUE OCCURS WITH UP TO THREE MINUTES EXPOSURE - CAUSES BURNS (R34) - FULL THICKNESS DESTRUCTION OF SKIN TISSUE OCCURS WITH UP TO FOUR HOURS EXPOSURE - NO REFERENCE TO CORROSIVITY TO METALS

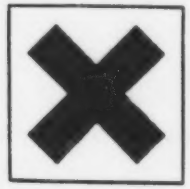
CLASSIFICATION: COMBUSTIBLE LIQUID

CPR SECTION 38	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS B, DIVISION 3		- NO SYMBOL SPECIFIED
CRITERIA	- 37.8°C ≤ FLASHPOINT < 93.3°C (100°F) (200°F)	- NOT CLASSIFIED	- FLAMMABLE 21°C ≤ FLASHPOINT < 55°C (R10) - NOT IF IT CANNOT SUPPORT COMBUSTION AND WILL NOT POSE A FIRE RISK TO HANDLERS

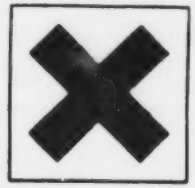
CLASSIFICATION: DANGEROUSLY REACTIVE MATERIAL

CPR SECTION 66	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS F		
CRITERIA	A) UNDERGOES VIGOROUS POLYMERIZATION, DECOMPOSITION OR CONDENSATION B) BECOMES SELF-REACTIVE UNDER CONDITIONS OF SHOCK OR INCREASE IN PRESSURE OR TEMPERATURE C) REACTS VIGOROUSLY WITH WATER TO PRODUCE A GAS WITH AN LC50 $\leq$ 2500 PPM	- NOT CLASSIFIED	- NO DANGEROUSLY REACTIVE CRITERIA - ARE SOME RISK PHRASES DEFINED: - CONTACT WITH WATER LIBERATES TOXIC GAS (R30) - REACTS VIOLENTLY WITH WATER (R14) - CONTACT WITH ACID LIBERATES TOXIC (R31), VERY TOXIC (R32) GAS

CLASSIFICATION: MUTAGENICITY

CPR SECTION 62	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2		Xn 
CRITERIA	- SUBDIVISION B, TOXIC - EVIDENCE OF MUTAGENICITY IN MAMMALIAN SOMATIC CELLS IN VIVO IS OBTAINED IN SPECIFIED TESTS ASSESSING GENE MUTATION OR CHROMOSOMAL ABERRATION	- NOT CLASSIFIED	HARMFUL - CATEGORY 2 (R46) - A STRONG PRESUMPTION CAN BE MADE THAT HUMAN EXPOSURE MAY RESULT IN HERITABLE GENETIC DAMAGE ON THE BASIS OF APPROPRIATE ANIMAL STUDIES - CATEGORY 3 (R40) - EVIDENCE DOES NOT SATISFACTORILY DEMONSTRATE HERITABLE GENETIC DAMAGE

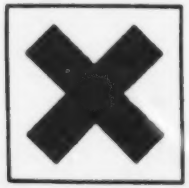
CLASSIFICATION: SKIN OR EYE IRRITATION

CPR SECTION 60	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	Xi 
CRITERIA	- SUBDIVISION B, TOXIC SKIN — OECD 404 GRADE A) ERYTHEMA FORMATION ≥ 2 EDEMA FORMATION ≥ 2 EYES — OECD 405 GRADE B) CORNEAL DAMAGE ≥ 2 IRIS DAMAGE ≥ 1 CONJUNCTIVAL SWELLING, REDNESS ≥ 2.5	- NOT CORROSIVE BUT CAUSES A REVERSIBLE INFLAMMATORY EFFECT AT POINT OF CONTACT ON LIVING TISSUE. - COULD INCLUDE LUNG IRRITANTS SKIN - SCORE OF 5 OR MORE IN 16 CFR 1500.41 (SCORE ADAPTED FROM DRAIZE TEST) EYES - IF SO DETERMINED BY 16 CFR 1500.42 OR OTHER APPROPRIATE TECHNIQUES - MORE SERIOUS RISK OF SKIN AND EYE DAMAGE WOULD BE COVERED IN EVALUATION OF CUTANEOUS AND EYE TARGET ORGAN SYSTEMS	- SKIN (R38) - OECD GRADES - SAME AS WHMIS - SIGNIFICANT INFLAMMATION IS CAUSED AND REMAINS PRESENT FOR MORE THAN 24 HOURS - EYES (R36) - SIGNIFICANT OCULAR LESIONS ARE CAUSED AND REMAIN PRESENT FOR MORE THAN 24 HOURS CORNEAL DAMAGE $2 \leq$ GRADE < 3 IRIS DAMAGE $1 \leq$ GRADE < 1.5 CONJUNCTIVAL REDNESS ≥ 2.5 CONJUNCTIVAL OEDEMA ≥ 2 - SERIOUS DAMAGE TO EYES (R41) SEVERE CORNEAL DAMAGE - GRADE ≥ 3 IRIS LESIONS - GRADE ≥ 1.5 - SERIOUS RESPIRATORY IRRITANT (R37)

CLASSIFICATION: MUTAGENICITY

CPR SECTION 57	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2		T T+
CRITERIA	- SUBDIVISION A, VERY TOXIC A) EPIDEMIOLOGICAL EVIDENCE OF HERITABLE GENETIC EFFECTS B) EVIDENCE OF MUTAGENICITY IN MAMMALIAN GERM CELLS IN VIVO, IN ACCORDANCE WITH SPECIFIED TEST METHODS	- NOT CLASSIFIED - SIGNIFICANT EVIDENCE OF MUTAGENICITY LIKELY TO BE COVERED IN EVALUATING DATA ON THE REPRODUCTIVE TARGET ORGAN SYSTEM - BACTERIA MUTAGENICITY TESTS (EG AMES TESTS) SHOULD BE CITED	- TOXIC, VERY TOXIC CATEGORY 1 - SUBSTANCES KNOWN TO BE MUTAGENIC IN MAN, I.E. DEFINITE EVIDENCE OF HERITABLE GENETIC DAMAGE (R46)

CLASSIFICATION: RESPIRATORY TRACT SENSITIZATION

CPR SECTION 56	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	Xn 
CRITERIA	- SUBDIVISION A, VERY TOXIC - EVIDENCE OF RESPIRATORY TRACT SENSITIZATION FOLLOWING WORKPLACE EXPOSURE	- SENSITIZER - CAUSES A SUBSTANTIAL PORTION OF EXPOSED PEOPLE OR ANIMALS TO DEVELOP AN ALLERGIC REACTION TO NORMAL TISSUE AFTER REPEATED EXPOSURE I.E. SKIN AND LUNG SENSITIZERS ARE COVERED IN THIS CLASSIFICATION	- HARMFUL - CAPABLE OF INDUCING SENSITIZATION REACTION IN HUMANS BY INHALATION AT A GREATER THAN EXPECTED FREQUENCY THAN IN NORMAL POPULATION (R42)

CLASSIFICATION: CARCINOGENICITY

CPR SECTION 54	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T Xn
CRITERIA	- SUBDIVISION A, VERY TOXIC A) LISTED IN SECTION A1A, A1B, OR A2 IN ACGIH TLV'S FOR CHEMICAL SUBSTANCES AND PHYSICAL AGENTS IN THE WORK ENVIRONMENT. B) LISTED IN GROUP 1 OR 2 IN THE IARC MONOGRAPHS ON THE EVALUATION OF THE CARCINOGENIC RISK OF CHEMICALS TO HUMANS	- LISTED AS A CARCINOGEN OR POTENTIAL CARCINOGEN BY A) IARC B) NTP, OR C) REGULATED AS CARCINOGEN BY OSHA	- TOXIC, VERY TOXIC CATEGORY 1 (R45) - SUBSTANCES KNOWN TO BE CARCINOGENIC TO MAN (e.g. IARC GROUP 1) CATEGORY 2 (R45) - SUBSTANCES WHICH SHOULD BE REGARDED AS CARCINOGENIC TO MAN ON THE BASIS OF STRONG EVIDENCE(e.g. IARC GROUP 2) - HARMFUL CATEGORY 3 (R40) - SOME EVIDENCE OF CARCINOGENIC POTENTIAL BUT INSUFFICIENT TO CLASSIFY (e.g. IARC GROUP 3)

CLASSIFICATION: REPRODUCTIVE TOXICITY

CPR SECTION 55	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- SUBDIVISION A, VERY TOXIC A) EVIDENCE OF STERILITY OR ADVERSE EFFECT ON REPRODUCTIVE CAPABILITY FOLLOWING WORKPLACE EXPOSURE. OR B) IF SAME EVIDENCE IS SHOWN ONE OR TWO GENERATION REPRODUCTIVE TOXICITY ANIMAL ASSAYS	- NO SPECIFIC CRITERIA - WOULD BE INCLUDED IN REPRODUCTIVE TOXIN, TARGET ORGAN CATEGORIZATION	- NO SPECIFIC CRITERIA - CONSIDER CHRONIC TOXIC EFFECT CRITERIA

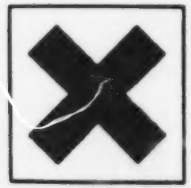
CLASSIFICATION: SKIN SENSITIZATION

CPR SECTION 61	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- SUBDIVISION B, TOXIC A) OECD 406 - PRODUCES RESPONSE IN ≥ 30% OF TEST ANIMALS WITH USE OF AN ADJUVANT - PRODUCES RESPONSE IN ≥ 15% OF TEST ANIMALS WITHOUT USE OF AN ADJUVANT B) POSITIVE EVIDENCE OF WORKPLACE SKIN SENSITIZATION	- SKIN AND LUNG SENSITIZERS COVERED UNDER SENSITIZER CLASS -- SEE RESPIRATORY SENSITIZATION	- IRRITANT (R43) - IF SENSITIZATION REACTION IS NOTED IN A SIGNIFICANT HUMAN OR ANIMAL POPULATION FOLLOWING EXPOSURE - SAME OECD 406 TEST RESULTS CONSIDERED

CLASSIFICATION: BIOHAZARDOUS INFECTIOUS MATERIAL

CPR SECTION 64	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 3		
CRITERIA	- AN ORGANISM AND ITS TOXINS THAT HAS BEEN SHOWN OR IS BELIEVED TO CAUSE DISEASE IN PERSONS OR ANIMALS	- NOT CLASSIFIED	- NOT CLASSIFIED

CLASSIFICATION: CHRONIC TOXIC EFFECTS

CPR SECTION 59	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	Xn 
CRITERIA	- SUBDIVISION B, TOXIC - EFFECTS OF SUFFICIENT SEVERITY TO THREATEN LIFE OR CAUSE SERIOUS PERMANENT IMPAIRMENT IN ≥ 90 DAY TESTS AT: A) 10 MG/KG/DAY < ORAL DOSE ≤ 100 MG/KG/DAY B) 20 MG/KG/DAY < DERMAL DOSE ≤ 200 MG/KG/DAY C) GASES AND VAPOURS: 25 PPM < INHALATION CONC. ≤ 250 PPM DUST, MIST, FUME: 10 MG/M^3 < INHALATION CONC. ≤ 100 MG/M^3	- NO CRITERIA SPECIFIED - TARGET ORGAN EFFECTS CONSIDERED	- HARMFUL - (R48) DANGER OF FUNCTIONAL DISTURBANCE OR MORPHOLOGICAL CHANGE BY REPEATED OR PROLONGED EXPOSURE AT: A) ORAL DOSE ≤ 50 MG/KG/DAY B) DERMAL DOSE ≤ 100 MG/KG/DAY C) INHALATION CONC. ≤ 500 MG/M^3 - APPLY DIRECTLY TO 90 DAY SUB-CHRONIC GUIDELINES TO INTERPRET SUB-ACUTE (28 DAY) OR CHRONIC (2 YEARS) STUDIES

CLASSIFICATION: COMPRESSED GAS

CPR SECTION 34	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS A	- NO HAZARD SYMBOL RECOMMENDED IN ANSI STANDARD ON PRECAUTIONARY LABELLING	- NOT CLASSIFIED
CRITERIA	A) CRITICAL TEMPERATURE $<50^{\circ}C$ B) ABSOLUTE VAPOUR PRESSURE >294 kPa at $50^{\circ}C$ C) ABSOLUTE PRESSURE IN PRESSURE VESSEL >275 kPa at $21.1^{\circ}C$ OR >717 kPa at $54.4^{\circ}C$ D) IN LIQUID STATE ABSOLUTE VAPOUR PRESSURE >275 kPa at $37.8^{\circ}C$ (ASTM P. 323-82, 1981)	- NOT SPECIFIED - NOT SPECIFIED - SAME AS WHMIS CRITERIA >40 psi at $70^{\circ}F$ >104 psi at $130^{\circ}F$ >40 psi at $100^{\circ}F$	- NOT CLASSIFIED

CLASSIFICATION: FLAMMABLE GAS

CPR SECTION 36	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS B, DIVISION 1	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- COMPRESSED GAS WHICH FORMS FLAMMABLE MIXTURE WITH AIR AT ATMOSPHERIC PRESSURE A) AT <13% VOLUME OR B) OVER A 12% CONCENTRATION RANGE	- SAME AS WHMIS CRITERIA	- HIGHLY FLAMMABLE A GAS WHICH IS FLAMMABLE IN AIR AT NORMAL PRESSURE WOULD BE LABELLED EXTREMELY FLAMMABLE (R12) UNDER THE HIGHLY FLAMMABLE CLASS - INCLUDES EXTREMELY FLAMMABLE LIQUEFIED GASES (R13)

CLASSIFICATION: FLAMMABLE SOLID

CPR SECTION 39	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS B, DIVISION 4	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	A) CAUSES FIRE THROUGH FRICTION OR RETAINED HEAT FROM PROCESSING B) WILL READILY IGNITE AND BURNS VIGOROUSLY C) IGNITES READILY AND BURNS AT A RATE > 0.254 CM/SECOND (0.1 INCH/SECOND) ALONG ITS MAJOR AXIS D) IS INCLUDED IN DIVISION 1 OF CLASS 4 OF PART III, TDG	- SAME AS WHMIS CRITERIA, PLUS - WILL CAUSE FIRE FROM: ABSORPTION OF MOISTURE OR SPONTANEOUS CHEMICAL CHANGE	- HIGHLY FLAMMABLE WILL READILY IGNITE AND CONTINUE TO BURN (R11)

CLASSIFICATION: FLAMMABLE AEROSOLS

CPR SECTION 40	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS B, DIVISION 5	- FLAME SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	- PACKAGED IN AEROSOL CONTAINER - WHEN TESTED (SCHEDULE VI) YIELDS A FLAME PROJECTION AT FULL VALVE OPENING OR A FLASHBACK AT ANY DEGREE OF VALVE OPENING	- SAME AS WHMIS CRITERIA - SAME AS WHMIS CRITERIA	- CLASSIFIED UNDER DIFFERENT REGULATION FLAMMABLE IF: - CONTAIN FLAMMABLE GAS - LIQUIDS WITH FLASHPOINT LESS THAN 100°C - CONTAINER CONTENT ≥45 WT % OR ≥250 g OF FLAMMABLE COMPONENTS

CLASSIFICATION: REACTIVE FLAMMABLE MATERIALS

CPR SECTION 41	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS B, DIVISION 6		
CRITERIA	A) SPONTANEOUSLY COMBUSTIBLE UNDER NORMAL CONDITIONS OR LIABLE TO HEAT IN CONTACT WITH AIR TO THE POINT OF BURNING B) EMITS A FLAMMABLE GAS OR BECOMES SPONTANEOUSLY COMBUSTIBLE ON CONTACT WITH WATER OR WATER VAPOUR	- INCLUDED UNDER FLAMMABLE SOLIDS	- HIGHLY FLAMMABLE SPONTANEOUSLY FLAMMABLE IN AIR (R17) CONTACT WITH WATER LIBERATES HIGHLY FLAMMABLE GASES (R15)

CLASSIFICATION: OXIDIZING MATERIAL

CPR SECTION 42	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS C	- HAZARD SYMBOL NOT RECOMMENDED IN ANSI STANDARD ON PRECAUTIONARY LABELLING	
CRITERIA	A) CAUSES OR CONTRIBUTES TO THE COMBUSTION OF ANOTHER MATERIAL BY YIELDING OXYGEN OR ANY OTHER OXIDIZING MATERIAL B) IS AN ORGANIC PEROXIDE CONTAINING O-O STRUCTURE	- SAME AS WHMIS CRITERIA - ORGANIC PEROXIDES CLASSED SEPARATELY	(R11) ORGANIC PEROXIDES HAVING FLAMMABLE PROPERTIES IN THEMSELVES (R8) CONTACT WITH COMBUSTIBLE MATERIAL MAY CAUSE FIRE (R9) EXPLOSIVE WHEN MIXED WITH COMBUSTIBLE MATERIAL

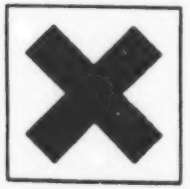
CLASSIFICATION: ACUTE LETHALITY

CPR SECTION 49	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 1	- SKULL AND CROSSBONES SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T
CRITERIA	- SUBDIVISION B, TOXIC A) 50 MG/KG < ORAL LD50 ≤ 500 MG/KG B) 200 MG/KG < DERMAL LD50 ≤ 1000 MG/KG C) INHALATION - VAPOUR (4 HR) 1500 PPM < LC50 ≤ 2500 PPM D) INHALATION - DUST, MIST, FUME (4 HR) 500 MG/M^3 < LC50 ≤ 2500 MG/M^3	- TOXIC A) ORAL - SAME AS WHMIS B) DERMAL - SAME AS WHMIS C) INHALATION - VAPOUR or GAS (1 HR) 200 PPM < LC50 ≤ 2000 PPM INHALATION - DUST, FUME, MIST (1 HR) 2000 MG/M^3 < LC50 ≤ 20,000 MG/M^3	- TOXIC - 25 MG/KG < ORAL LD50 ≤ 200 MG/KG (R25) - 50 MG/KG < DERMAL LD50 ≤ 400 MG/KG (R24) - INHALATION (R23) (4 HR) 500 MG/M^3 < LC50 ≤ 2000 MG/M^3 - SERIOUS NON-LETHAL ACUTE EFFECTS AT SIMILAR DOSES (R39)

CLASSIFICATION: ACUTE LETHALITY

CPR SECTION 46	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 1	- SKULL AND CROSSBONES SYMBOL ACCEPTABLE ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T+
CRITERIA	- SUBDIVISION A, VERY TOXIC A) ORAL LD50 $\leq$ 50 MG/KG B) DERMAL LD50 $\leq$ 200 MG/KG C) GASES LC50 $\leq$ 2500 PPM (4 HR) D) VAPOURS LC50 $\leq$ 1500 PPM (4 HR) E) DUST, MIST, FUME, LC50 $\leq$ 500 MG/M^3	- HIGHLY TOXIC A) ORAL - SAME AS WHMIS B) DERMAL - SAME AS WHMIS C) INHALATION GAS AND VAPOUR (1 HR) LC50 $\leq$ 200 PPM DUST, MIST, FUME (1 HR) LC50 $\leq$ 2000 MG/M^3	- VERY TOXIC - ORAL LD50 $\leq$ 25 MG/KG (R28) - DERMAL LD50 $\leq$ 50 MG/KG (R27) - INHALATION LC50 $\leq$ 500 MG/M^3 (R26) (4 HR) - SERIOUS NON-LETHAL ACUTE EFFECTS AT SIMILAR DOSES (R39)

CLASSIFICATION: ACUTE LETHALITY

CPR SECTION	WHMIS	OSHA	EEC
HAZARD SYMBOL			Xn 
CRITERIA	- SOME OVERLAP WITH ORAL AND DERMAL ACUTE LETHALITY, TOXIC CRITERIA	- SOME OVERLAP WITH ORAL AND DERMAL ACUTE LETHALITY, TOXIC CRITERIA	- HARMFUL - 200 MG/KG < ORAL LD50 ≤ 2000 MG/KG (R22) - 400 MG/KG < DERMAL LD50 ≤ 2000 MG/KG - INHALATION (R20) (4 HR) 2000 MG/M^3 < LC50 ≤ 20,000 MG/M^3 - SERIOUS NON-LETHAL ACUTE EFFECTS AT SIMILAR DOSES (R40)

CLASSIFICATION: CHRONIC TOXIC EFFECTS

CPR SECTION 52	WHMIS	OSHA	EEC
HAZARD SYMBOL	CLASS D, DIVISION 2	- HAZARD SYMBOL NOT RECOMMENDED ACCORDING TO ANSI STANDARD ON PRECAUTIONARY LABELLING	T
CRITERIA	- SUBDIVISION A, VERY TOXIC - EFFECTS WITH SUFFICIENT SEVERITY TO THREATEN LIFE OR CAUSE SERIOUS PERMANENT IMPAIRMENT IN ≥ 90 DAY TESTS AT: A) ORAL DOSE ≤ 10 MG/KG/DAY B) DERMAL DOSE ≤ 20 MG/KG/DAY C) INHALATION CONCENTRATION ≤ 25 PPM GAS OR VAPOUR ≤ 10 MG/M^3 DUST, MIST, FUME	- NO CRITERIA SPECIFIED - MUST CONSIDER SPECIFIC TARGET ORGAN EFFECTS FROM ALL SOURCES OF INFORMATION	- TOXIC - CLEAR FUNCTIONAL DISTURBANCE OR MORPHOLOGICAL CHANGE WHICH HAVE TOXICOLOGICAL SIGNIFICANCE LIKELY TO BE CAUSED BY REPEATED OR PROLONGED EXPOSURE AT DOSES SIGNIFICANTLY LOWER THAN HARMFUL CLASS DOSES (R48)

References

Application of Criteria for Skin & Eye Irritation by R Morris

Draize Test. The Journal of Pharmacology and Experimental Therapeutics. Volume 82: pp. 337-390 (1944).

Controlled Products Regulations. Registration SOR/88-66. 31 December 1987.

FDA Draize Test. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. The Editorial Committee of the Association of Food and Drug Officials of the United States. pp. 46-52.

Grant, W. Morton. Toxicology of the Eye. Charles C. Thomas Publishers, Springfield, Ill., USA., (1974).

Methods of Testing Skin and Eye Irritants (Consumer Product Safety Commission). Federal Hazardous Substances Act and Regulations. Title 16. Part 1500.42-.43.

Occupational Safety and Health Administration (OSHA). Hazard Communication: Final Rule. Federal Register 48 (228): 53340-48.

Organisation for Economic Co-operation and Development (OECD) Test Guidelines, Numbers 404 (Dermal Irritation/Corrosion) and 405 (Eye Irritation/Corrosion) (1981).

Patty's Industrial Hygiene and Toxicology. 3rd Revised Edition (ed. G. D. and F. E. Clayton). Wiley-Interscience Publication, New York, (1981).

Registry of Toxic Effects of Chemical Substances (RTECS). NIOSH Publication No. 80-102.

Sax, N. Irving. Dangerous Properties of Industrial Materials. 6th Edition. Van Nostrand Reinhold Co., New York, (1984).